

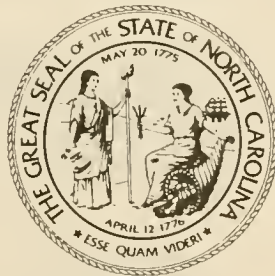
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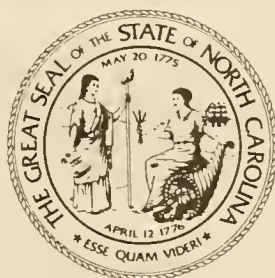
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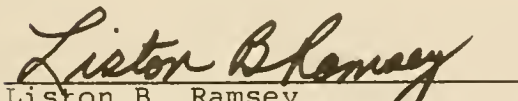


June 7, 1984

TO THE MEMBERS OF THE 1983 GENERAL ASSEMBLY:

This is the Legislative Research Commission's report to the 1983 General Assembly, Second Regular Session 1984, on biotechnology development. This report is made pursuant to Section 12 of 1983 Session Laws Chapter 905 (HB 1142), was prepared by the Legislative Research Commission's Biotechnology Study Committee, and is transmitted by the Legislative Research Commission for your consideration.

Respectfully submitted,


Liston B. Ramsey
Speaker of the House


W. Craig Lawing
Senate President Pro Tempore

Cochairmen
Legislative Research Commission

TABLE OF CONTENTS

Introduction

Interim Findings of the Committee	1
Interim Recommendations for the 1984 Session	4
Summary of Interim Report and Recommendations	7
Biotechnology: What Is It and Why Is It So Important?.....	11
Proceedings of the Committee	17
Future Activities of the Committee	31

APPENDICES

- A. Membership: Legislative Research
Commission; Biotechnology Study
Committee
- B. Senate Joint Resolution 620
- C. House Joint Resolution 1282
- D. Chapter 899, 1983 Session Laws
(House Bill 1122)
- E. Memorandum of Committee Counsel to Members
of the Biotechnology Study Committee,
January 27, 1984
- F. Memorandum of Steven Rose and Laura Meagher to
Members of the Biotechnology Study Committee,
February 17, 1984
- G. Tables Illustrating Estimated Annual Returns
and Impacts of Research and Extension Investments
In U.S. Agriculture

INTRODUCTION

The Legislative Research Commission, originally created in 1965 and authorized by Article 6B of Chapter 120 of the General Statutes is authorized, pursuant to the direction of the General Assembly, "to make or cause to be made such studies of and investigations into governmental agencies and institutions and matters of public policy as will aid the General Assembly in performing its duties in the most efficient and effective manner" and "to report to the General Assembly the result of the studies made," which reports "may be accompanied by the recommendations of the Commission and bills suggested to effectuate the recommendations." G.S. 120-30.17. The Commission is chaired by the Speaker of the House and the President Pro Tempore of the Senate, and consists of five Representatives and five Senators who are appointed respectively by the Cochairmen. G.S. 120-130.10(a).

Chapter 905 of the 1983 Session Laws (House Bill 1142) authorized the Legislative Research Commission to study, among other subjects, biotechnology development as outlined in Senate Joint Resolution 620 (Appendix B) and House Joint Resolution 1282 (Appendix C), and as specified in Chapter 899 of the 1983 Session Laws (House Bill 1122), which created the New Technology Jobs Act (Appendix D). Section 6 of Chapter 905 authorizes a report to the 1984 or 1985 Sessions of the General Assembly, or in the alternative

permits an interim report to the 1984 Session and a final report to the 1985 Session. For the reasons stated further on in this report, the Biotechnology Study Committee has chosen to make this interim report, and will make its final report to the 1985 Session.

The Joint Resolutions referred to above called for the study committee to review the projections that biotechnology will have a pervasive impact on various industries, as well as other areas; to review the steps being taken by other states to strengthen their positions in biotechnology; to review the present status of and further plans for biotechnology programs in the state's universities, the North Carolina Biotechnology Center, the Department of Commerce, the state's business community, and other organizations concerned with the development of biotechnology in the state; to review the development of the federal guidelines for safe conduct of research and development in this area, as well as the experiences of other states that have addressed that issue; and, finally, to "determine the short term and long term needs for North Carolina to be at the forefront of the technological and economic developments in the rapidly advancing field of biotechnology."

The study committee has spent some time looking at each of these issues, though it has by no means completed its work. The committee is making this interim report and set of recommendations in order to fulfill its mandate to determine the short term needs of the state to be "at the

forefront of technological and economic developments" in the area of biotechnology.

INTERIM FINDINGS OF THE COMMITTEE

The Biotechnology Study Committee makes the following findings based upon the testimony of numerous witnesses that have appeared before it, and other information supplied to it by its staff:

- I. That the projections that biotechnology will have a pervasive impact on industries such as pharmaceuticals, agriculture, forestry, chemicals, medical care, pollution control, and many other areas, are accurate. It is actually difficult to quantify the economic effect because biotechnology has the potential to affect so many areas. It will not only result in new products and processes, but it will also change the way many existing products are made or grown.
- II. That many other states have undertaken programs to strengthen their position in biotechnology in the areas of education, research, and financial and institutional support for biotechnology related development. There is also substantial activity on an international level, with countries such as Japan, the Federal Republic of Germany, the United Kingdom, Switzerland, and France gearing up national efforts to compete with the United States, which is perceived to be the leader in the commercialization of biotechnology. Within the

United States, there are two existing premier centers of strength in biotechnology, these being in Massachusetts and California. Otherwise, the field appears open to any state seeking a competitive position and at this time North Carolina appears to be in one of the best positions to capitalize on existing strengths and become a leader in this field, if it desires to do so.

III. That the universities of the state, public and private, are already involved in biotechnology related programs, with the emphasis varying from institution to institution, capitalizing on the existing strengths of each, with interaction and communication going on actively between them. The North Carolina Biotechnology Center is functioning actively and leveraging its funds effectively. The Department of Commerce has begun promoting the state as a biotechnology center along with its other economic promotion of the state. As a result of the activities of the Biotechnology Center and the Department of Commerce, there is already investment in the state by private companies concerned with biotechnology related activities.

IV. That there are short term needs in order for the state to maintain its present competitive position as a perceived leader in the field of

biotechnology, and in order to assist the state's universities in maintaining their reputations as international leaders in research and education.

It is anticipated that the final report of the Biotechnology Study Committee will contain additional findings and expand upon the ones contained in this report.

INTERIM RECOMMENDATIONS FOR THE 1984 SHORT SESSION

The Biotechnology Study Committee recommends that the actions which follow be taken by the Legislature and the appropriate administrative departments:

I. That \$2,960,000 be appropriated to the Office of State Budget and Management from the General Fund for Fiscal Year 1984-85 as a reserve. Upon the application of the University of North Carolina Board of Governors, and with the advice of the Advisory Budget Commission, the Governor may allot moneys from that reserve to the Board of Governors to recruit and hire four world class scientists or engineers whose work is related to biotechnology, to the University of North Carolina constituent universities, including, in addition to competitive salaries, the other components necessary to attract researchers of this caliber, such as start-up research funds and laboratory setup costs. These funds shall also be allotted to recruit and hire four, and possibly more, excellent junior professors whose work is related to biotechnology, and for the support of eight to ten postdoctoral fellows and eight to ten graduate student fellows to support the research efforts of the recruited scientists and other scientists in the university system already doing biotechnology related work.

II. That \$4,500,000 be appropriated to the Office of State Budget and Management from the General Fund for Fiscal Year 1984-85 as a reserve. Upon the application of the

University of North Carolina Board of Governors, and with the advice of the Advisory Budget Commission, the Governor may allot moneys from that reserve to the Board of Governors for capital improvements associated with the recruitment of these research scientists and for promoting interaction between university researchers, public and private, and industry. Such improvements could be in the form of laboratory space, bioprocessing pilot plant facilities, and planning of future research facilities.

III. That the appropriations recommended in paragraphs I. and II. not revert to the General Fund if unused at the end of the fiscal year, since recruitment of the people described and construction of the associated capital improvements may extend beyond that time.

IV. That \$1,965,000 be appropriated to the Department of Commerce for use by the North Carolina Biotechnology Center. These funds would be used for programs which facilitate university/industry interactions, thereby promoting technology transfer, and for substantial competitive grants or collaborative research programs which would be open to all research institutions, public and private. These funds would also be used to sponsor top quality conferences and workshops designed to enhance the perception of North Carolina as a leader in biotechnology, while at the same time adding to the expertise of university and industry researchers in this area.

V. That \$575,000 be appropriated to the Technological Development Authority which would allow the Authority to help establish at least two additional incubator facilities, which will provide support for beginning technology related businesses around the state, and to fund additional private business research support under its Innovation Research Fund program. The breakdown of these funds would be \$400,000 for incubator facilities and \$175,000 for the Innovation Research Fund.

SUMMARY OF INTERIM
REPORT AND RECOMMENDATIONS

The Biotechnology Study Committee has met five times and, while it will continue to meet with the aim of making a final report to the 1985 Legislative Session, it has become apparent that it is necessary to take some immediate action in order to preserve the state's position as a perceived leader in the field of biotechnology, and in order to assist the state's universities in maintaining their reputations as international leaders in research and education.

Testimony before the committee has shown conclusively that the worldwide effects of the biotechnology revolution will be pervasive, so much so that they have proved unquantifiable. In addition to the direct impact in such areas of importance to North Carolina as agriculture, forestry, pharmaceutical research and production, marine biology, and food processing, biotechnology techniques will alter the methods with which research is carried on in our universities.

The committee has heard reports of the actions being taken in other states to promote biotechnology, both in the areas of commerce and in university research and teaching, and feels that certain minimal actions are called for in the short term so as not to lose the momentum which has already been established by the work of the state's universities and the Biotechnology Center. The short term proposals

contained in this report do not commit the Legislature or any administrative department to any long range comprehensive program, although such a program has been proposed and is being considered by the committee. On the other hand, should the committee ultimately recommend a long range program and the Legislature agreed to adopt and fund such a program, the recommendations contained in this report will fit into that program, or any variation of it.

It should be pointed out that the universities of the state, public and private, have already made a strong commitment in the area of biotechnology related research simply because it is necessary in their view to do so in order to maintain their competence as institutions of higher learning.

The funds recommended for recruitment of world class and younger, but excellent professors and for post doctoral and graduate school fellows, as well as the recommendations for capital funding in support of biotechnology, are recommended to be appropriated to the Office of State Budget and Management as a non-reverting reserve fund so they will be available as needed, since it will take some time to actually recruit the recommended people once that process is begun, and the capital items will no doubt be determined, at least in part, by the types of scientists recruited. On the other hand, it is imperative that these funds be actually appropriated and available since recruitment of these people

and planning of these facilities could not proceed without that assurance.

With regard to the funds recommended for the North Carolina Biotechnology Center, it should be noted that based upon past performance the Center should easily generate additional funds from federal and private sources at least equivalent to the amount suggested for appropriation to it and, the Center would then be in a position to fulfil several important roles. It would help ensure that the university research which is already going on in the area of biotechnology, as well as the expanded research which would occur under this proposal, would result, where appropriate, in technology transfer to industry. The Center would also expand its role in sponsoring activities which would enhance the perception of North Carolina as a leader in biotechnology. This is a very important factor in bringing economic development to the state and was stressed by many speakers during the course of the committee's deliberations. Finally, the Center will be a vehicle for involving the private institutions in our state in the overall collaborative effort to develop in the area of biotechnology and to make certain that all of the state's institutions, private as well as public, will maintain and enhance their academic abilities and reputations. In the view of the study committee, this funding is necessary if there is going to be a meaningful, functioning Biotechnology Center. On the other hand, should the committee ultimately recommend a long range

and comprehensive biotechnology development program, the Biotechnology Center will be in a position to aid and coordinate such a program.

It should be stressed that these interim recommendations are not tied to any long range program. The committee has not reached the point of making a decision on whether or not to recommend such a program. However, the committee feels that the recommendations contained in this interim report represent the minimum that should be done to ensure that the state does not take a step backward in this most important area. The committee has designed its recommendations so that they can be part of a long range development program or they can stand alone.

With regard to the recommended funding for the Technological Development Authority, the Authority was created during the 1983 Session of the Legislature and was given funds for an incubator facilities program in the amount of \$200,000 for each year of the biennium, and for its Innovation Research Fund in the amount of \$225,000 for each year of the biennium. The widespread response to the Authority's first call for proposals, as well as the quality of the proposals, indicates that additional funding would be well used to assist beginning and expanding businesses in communities across the state. A significant portion of small business support requests received pertain to biotechnology. It should be pointed out that the Legislature would not be committing funds beyond fiscal year 1984-85.

BIOTECHNOLOGY: WHAT IS IT AND WHY IS IT SO IMPORTANT?

The development of biotechnology, the ability to manipulate components of a cell and reproduce the results, is a revolution in scientific, agricultural, biomedical, and manufacturing processes and techniques. It is not a new or separate scientific discipline. One way of looking at biotechnology is that it is a collection of new techniques, centering on biology, which make possible novel extensions and combinations of existing scientific disciplines and new industrial applications. These new techniques came about with the understanding of the structure of deoxyribonucleic acid (DNA), composing the genes of all organisms, combined with the ability to manipulate genes and reproduce the results of that manipulation.

These new techniques are revolutionizing many sciences and manufacturing processes and will have a pervasive effect on everyone's life in the very near future. It is important to understand that these techniques are already in use today. For example, on April 26, 1984, the New York Times Service newswire reported that a major biotechnology company, Genentech, Inc., announced that it had created in the laboratory a complex protein vital to the normal clotting of blood. It is the protein that is missing or deficient in hemophiliacs. Previously, the substance had to be extracted from donated blood. By using gene splicing and cloning techniques, that substance can now be produced artificially

and, as a by product of that research, scientists will be better able to study the molecular basis of hemophilia and possibly develop techniques for prenatal diagnosis of this hereditary disease. Insulin is another pharmaceutical product that can already be produced using biotechnology techniques. Such a product is presently undergoing clinical trials. Interferon, which is important to the body's immune functions and is thought to inhibit viral infections, can also already be produced using biotechnology techniques and is thought to hold great promise for such diverse results as a cure for the common cold and for certain kinds of cancer.

The importance of biotechnology in the areas of agriculture and forestry is enormous. Hybridization has always been at the forefront of progress in these areas, with scientists developing various strains of plants and trees having desirable characteristics for particular applications. These include faster growing varieties, disease, pest and drought resistance, and characteristics desirable for the ultimate use of the product, such as straight-growing knot-free trees. The problem has always been that the creation of these plants and trees through selective breeding has taken many, many years because of the need to go through the entire growing cycle for a number of plants (in trees this can be 20 years or more) and then attempting to select out the ones with the desirable traits and reproduce them again, refining the end product each time. Using

cloning techniques, this whole process can be shortened dramatically.

In the area of pharmaceuticals and medicine, the most intriguing idea which the committee heard is the so called "magic bullet" technique of disease treatment. This involves the possibility of producing drugs which will seek out only those cells within the body responsible for an illness and deliver medication to those cells without affecting the rest of the body. For example, in the treatment of cancer using chemotherapy, the present techniques involve the administration of drugs which are poisonous to the cancer cells. The problem is that once placed in the body the drugs also affect the other, noncancerous cells in the body. Hence, chemotherapy becomes a balancing act of administering enough of the treatment to kill the cancer causing cells without producing so much other damage in the patient's body that the patient is killed by the treatment. This is why success rates in chemotherapy treatment are erratic and why people experience such harsh side effects while undergoing treatment. Using biotechnology innovations, the desired treating agent could be attached to cells which would seek out only those cells in the body affected by the cancer, killing those cells but not the other healthy ones around them. This same technique would also lend itself to the production of all types of vaccines, some already produced by other means, others still in research stages.

In the areas of pollution control and waste management, biotechnology should lead to creation of substances which can break down pollutants or waste products into harmless products more easily disposed of. A so-called oil eating bacteria which can be used to clean up oil spills has already been produced and patented .

The production of chemicals will probably undergo one of the most important changes, although this is probably one of the longer range results from biotechnology research. At the present time, virtually all chemicals are petroleum based. In the future, however, it seems very likely that a biological, and therefore renewable, basis for chemical production will be developed, thus vastly reducing this country's, and the world's, dependence on oil.

The committee has heard that even such things as mining may some day be done with biological substances produced by biotechnology research. These would seek out and remove ores from the earth, having been developed to seek out only a particular mineral and separate it from other substances which surround it. This technique will probably never change the way we mine iron ore or coal, but it may very well change the way we seek out rare elements and precious metals useful to industry and science.

Research is presently going on to develop a biological basis of information storage for computers. Thus, the high technology field of computer development is already being viewed as capable of undergoing a further and more

revolutionary change than that which was brought about by the development of microelectronics.

The economic potential of all of this is so enormous as to be incalculable. Estimates of the value of biotechnology produced products by the year 2000 have ranged from 40 billion dollars to 100 billion dollars yearly. The point to be remembered is that not only will we have new products and processes, but that the greatest economic impact will come because of the development of new ways of making and growing existing products and performing existing processes. This means that there will be economic development not only because new businesses will be developed to produce new products, but also because existing businesses will be producing or processing their products by other than their traditional techniques. This will mean that they, too, must invest in new production and processing facilities.

The economic benefits to be realized come in the form of new investments by businesses and the related jobs and economic ripple effect from such investments, and in the form of direct benefits from the creation of products important to the economy of a given state. In the case of North Carolina, these direct benefits would be in the areas of agriculture, forestry, and pharmaceuticals, areas upon which the state is already greatly dependent for its economic well being.

Finally, if academically strong universities, public and private, are important to the well being of the people

of the state, the ability of those universities to participate in the biotechnology revolution is a necessity, because biotechnology related techniques will become part of basic research and teaching in many scientific disciplines. It is a necessity our universities have already recognized and begun to participate in to the extent that their resources allow.

PROCEEDINGS OF THE COMMITTEE

The Biotechnology Study Committee met a total of five times between December 1983 and May 1984. Due to the complex nature of the subject, and the number of people on the committee who needed to travel from various parts of the state to attend, the meetings were lengthy and the agendas quite full.

The first meeting of the committee covered a full one and one-half days on December 14 and 15, 1983. It was structured to educate the study committee on the subject of biotechnology, and to bring at least some information to the committee on most of the matters the committee was mandated to review.

The committee heard from the state's Commissioner of Agriculture and Secretary of Commerce, from high ranking officials of North Carolina State University and the University of North Carolina at Chapel Hill, as well as from persons associated with businesses having an interest in biotechnology. The program included a panel discussion by representatives of each institution of higher learning in North Carolina with a biotechnology program. The institutions represented were Duke University, North Carolina State University, University of North Carolina at Chapel Hill, East Carolina University, Bowman Gray Medical School/Wake Forest University, and the University of North Carolina at Wilmington. The director of the North Carolina

Biotechnology Center addressed the committee to review the state government programs related to biotechnology. He told the committee that the North Carolina Biotechnology Center is functioning well and leveraging its funds, the Department of Commerce is already promoting the state as a biotechnology center along with its other economic promotion of the state, and there is already some investment by private companies in our state.

The committee also heard from a member of the National Institute of Health's (NIH) Recombinant Advisory Committee (RAC). This is the committee which supervises and approves experiments which require approval under the guidelines. He told the committee that while the NIH guidelines are only applicable to federally funded research, they have been widely adopted on a voluntary basis by private companies and, thus far, neither the Congress, nor any of the states, have adopted legislation to regulate in this area. A few local governments have passed ordinances which adopt the NIH guidelines as their standard.

During the 12 hours it took to complete the agenda, the committee received information on each item it was requested to study. However, the committee was by no means ready to make any decisions, rather it was able to identify those areas which needed further study and deliberation. (At a subsequent meeting of the committee, on January 27, 1984, counsel to the committee presented a detailed summary of the

proceedings at the first meeting, which is included in this report. See Appendix E.)

It was obvious from the presentations at the first meeting of the committee that the larger companies are very much aware of the future impact of biotechnology and that smaller companies are becoming increasingly involved as well. It was also obvious that the academic institutions of the state are equally aware of the impact and are already developing individual biotechnology programs related to their particular strengths and institutional interests. There are also two functioning vehicles for interinstitutional communication, the North Carolina Biotechnology Center and the University Biotechnology Council.

An explanation of biotechnology and a brief review of its general, academic and economic importance, based on information received at the first meeting and supplemented by staff research, is set out in a separate section of this report. (See pages 11-16.)

The second meeting of the committee was held at the world headquarters of R. J. Reynolds Industries, Inc. (RJR) in Winston Salem, North Carolina, at the invitation of Dr. Roy E. Morse, a member of the study committee and the senior vice president for research and development at RJR. Since the committee had been told of the universities' needs for sophisticated research facilities if the state was to be at the forefront of technological and economic developments in the field of biotechnology, Dr. Morse thought it would be

helpful for the members of the committee to tour the recently completed research and development facilities at RJR.

In addition to the members of the committee and other interested persons attending the meeting being able to tour this impressive facility, the committee met formally and, after reviewing the ideas and concerns expressed at its first meeting, heard a report on activities in biotechnology in other states, as well as a presentation from Dr. Morse and members of the RJR research and development staff on how a large company looks at biotechnology.

In the report on efforts in other states, the committee heard that there is much activity around the country to promote biotechnology and capitalize on its economic effects. The approaches vary, with some being merely acknowledgements of the desire to be a part of the biotechnology future, while others represent specific steps being taken to strengthen universities and promote economic development. Some of these efforts involve investment of considerable funds by government with extensive participation by private industry. Implicit in the review of activities in other states is the fact that many states are aware of the coming biotechnology future and want a piece of it, but some states are clearly ahead of others in their efforts to capitalize on it. During the research for that report, it also became apparent that North Carolina was perceived as one of the states that had already taken positive steps to promote

biotechnology, and thus was considered to be a strongly positioned competitor.

(Shortly after this meeting, the members of the committee received copies of a summary of a recent report published by the Office of Technology Assessment of the Congress of the United States entitled Commercial Biotechnology: An International Analysis (January 1984). This report showed that there is also intense competition in the commercialization of biotechnology on an international level and, while the United States was considered to be the current world leader in commercial biotechnological development, Japan, the Federal Republic of Germany, the United Kingdom, Switzerland, and France all had governmentally supported biotechnology development programs underway which could make them major competitors of the United States in this area.)

In the discussion which followed, the committee members indicated that it would be most helpful for them to have a document before them which would pull together the different proposals suggested to them at their first meeting, augmented by the information on activities in other states, as the means to make North Carolina a leader in biotechnology and a recipient of the potential economic benefits. It appeared to the committee that the suggestions made by the various speakers at the first meeting were not in conflict with each other, but rather could form the parts of a possible comprehensive approach. The committee instructed the staff to

prepare such a document, in consultation with representatives of the state's universities, the Governor's Science and Public Policy Advisor, and other appropriate individuals, in time for its next meeting on February 24, 1984.

The thrust of testimony and other information presented to the committee through the time of its second meeting was that North Carolina was in a very competitive position to place itself among the leaders in biotechnology and, if this was done, the result would be investment in the state by biotechnology related businesses, as well as direct benefits to the state in the areas where it already has a strong proprietary interest, such as agriculture and forestry. The committee had been told that, in order to achieve these results, the state needed to make itself a center of excellence in biotechnology. This would require a multifaceted plan strengthening the programs of the universities, both public and private, and promoting interaction between the universities and industry. It would also require making certain these efforts were known worldwide.

The committee staff took the various suggestions of the witnesses who had appeared before the committee and put them into the form of a comprehensive plan which could be accomplished over a period of five years. It was felt that if the effort were stretched out much longer our competitive edge would be lost to others. This plan was prepared in the form of a memorandum, dated February 17, 1984, which was formally presented to the committee at its meeting on

February 24, 1984. A copy of that memorandum is a part of this report. See Appendix F.

It must be stressed that the memorandum does not represent the recommendations of the committee. Rather, it is a discussion piece around which the committee can structure its further deliberations. As will be seen further on in this report, there are many questions the committee must answer before it could recommend any long term development effort in the area of biotechnology. This is why the committee was particularly careful to structure its short term recommendations in such a way that they could both fit into a long range plan or stand alone if it were ultimately determined that the state should not undertake a comprehensive long range effort in biotechnology.

The bulk of the committee's time at its February 24, 1984 meeting was spent in receiving this discussion piece and having the committee staff review it with the committee. Representatives of the various state universities, public and private, made brief comments to the committee giving their initial reactions to the memorandum. Many of these representatives supplemented their comments with written statements which are a part of the committee's minutes. The university representatives were generally supportive of the proposals and felt that their input in the committee's proceedings had been fairly and accurately represented.

The members of the committee now turned their attention to what the next steps should be now that a document had

been prepared embodying the various proposals and ideas that had been presented to them. They wanted to be sure that the dollar estimates for implementation were reasonably accurate, that such a set of proposals would indeed result in an economic benefit to the people of the state, and that the economic benefit could be spread across the state equitably. To the end of answering these questions, the committee asked its counsel to refer the memorandum to the Legislature's Fiscal Research Division for its scrutiny. The committee also asked its staff to seek out reaction to the proposals from the very industries and businesses, large and small, the state would seek to recruit, in order to find out if something like these proposals would be attractive to them.

The next meeting of the committee, on April 19, 1984, was structured to respond primarily to the committee's specific request for information on the attractiveness of the proposals which had been presented to it. This was another eight hour agenda during which the committee heard from a variety of corporate executives, including people associated with such major companies as Burroughs Wellcome and E.I. duPont de Nemours, the Director of Corporate Development of IGEN, Inc., a biotechnology venture company (who was formally Manager of Advanced Technology for CIBA-GEIGY with responsibility for planning and implementing its biotechnology related commitments in agriculture), and executives of North Carolina corporations with a strong interest in biotechnology. The committee also heard from J.

Tomas Hexner, a businessman who specializes in working with scientists in the organization and operation of for profit corporations, with extensive experience in organizing biotechnology related companies. Finally, supplementing those speakers, the committee heard from Dr. Laura Meagher, Acting Administrator of the North Carolina Biotechnology Center, who had undertaken a telephone survey of executives of other companies which included venture companies involved exclusively in biotechnology, major pharmaceutical and chemical companies with a strong interest in biotechnology, forestry products companies, venture capitalists, the investment firm E.F. Hutton, and the Industrial Biotechnology Association. Since the specific comments and criticisms of the speakers before the committee and the additional persons contacted by Dr. Meagher will be taken up in the second phase of the committee's work, described further on in this report, they will not be reviewed in detail at this point. However, it can be stated that their reactions to the proposals were overwhelmingly positive. Of course, most of the business people reacting to proposals stressed that there was competition for biotechnology related economic development and that there were no guarantees of success for anyone. In addition, many of them pointed out that there are other factors which are basic to attracting all types of economic development, such as the quality of life in the state, basic "hard" infrastructure (transportation and utilities), a favorable tax structure, a

willing work force and the ability to train those workers. Overall, the input was optimistic on the question of the high economic potential of biotechnology and on the ability of an effort such as that proposed to attract a healthy share of the expected commercial development.

The committee did not wish to lose sight of the fact that in addition to attracting new or expanded economic development related to biotechnology, it had also been told that there could be direct benefits to some very important areas of North Carolina's economic life, specifically, agriculture and forestry. To gain more insight into the extent of the economic return which could be expected in these areas from a major investment in biotechnology research, the committee heard from Dr. A. Frank Bordeaux, Chief Economist of the North Carolina Department of Agriculture, who was able to speak to the question of whether or not there would be a greater return to the state's agriculture and forestry industries from investments in research in the state, as opposed to those agriculture and forestry interests merely taking advantage of research done in other states. His report showed that there is a greater return on investment in agricultural research to the agricultural interests in the state where the research is done, provided, of course, that the research relates to products which can be grown in that state. Dr. Bordeaux illustrated his talk with tables showing rates of return on agricultural research

for various time periods and in various areas of the country. They are included in this report as Appendix G.

The committee also heard from the Legislature's Fiscal Research Division. The Director of the Fiscal Research Division stressed that the Division stood ready to assist the committee as it delved further into the question of whether or not the economic benefits to the state were sufficient to justify the implementation of a long range biotechnology development program, and how the benefits of such a program might be spread across the state. Regarding the dollar estimates for implementing the proposals, the Division's research indicated that the figures appeared to be reasonable for the items proposed. They expressed some reservation as to whether all the items were needed. This aspect of the committee's deliberations will be taken up in the further proceedings of the committee.

The committee recognized that it was faced with two substantial questions related to whether or not there should be a long range development plan for biotechnology in North Carolina. No one questioned the pervasive impact of biotechnology directly on the lives of the people of the state, and in agriculture, forestry, pharmaceuticals and other areas already important to the state's economic life, but there was a strong desire to pursue further the question of whether or not the expenditure of state funds for a long range development program focusing on biotechnology would result in a sufficient economic return to justify the

expenditure, and whether or not that economic development could be spread across the entire state in a balanced way. The question of how to explore these factors had come up in previous discussions of the committee and Dr. Quentin Lindsey, the Governor's Science and Public Policy Advisor, had prepared a set of suggestions which he presented to the committee. Basically, those suggestions embodied the formation of an advisory committee to the Biotechnology Study Committee, composed of executives of in-state banking corporations and investment houses, members of the faculties of the business schools of some of the state's universities, public and private, and corporate executives of biotechnology companies. Their task would be to advise the committee on the economic value to the state of a long range investment in biotechnology, and, if such a strategy had sufficient economic value, whether the proposals before the committee would accomplish the purpose of attracting economic development. To that end, the advisory committee would recommend any changes in the proposals it thought necessary. If the economic return justified such an investment by state government, the advisory committee would suggest to the study committee how it could be made in such a way that the economic benefit could be spread across the state. The discussion which followed indicated that the committee members looked favorably upon Dr. Lindsey's proposal.

At this point, the committee discussion turned to the fact that, if the committee were to make any recommendation

to the short session of the Legislature, its time was running short. The committee was mindful of the fact that there was intense competition in other states to garner potential economic development from biotechnology, and that the universities of the state were concerned with maintaining their places in the development of biotechnology related programs. Also, Mr. William Veeder, a member of the committee and a member of the Board of Directors of the North Carolina Technological Development Authority, which was created by the General Assembly during the 1983 Legislative Session, had brought to the attention of the committee the Authority's need for increased funding for its programs, which he felt dovetailed with the efforts of the Biotechnology Study Committee. Both their incubator facilities program and their Innovation Research Fund were designed to assist small business development related to various kinds of technology in such a way that economic benefits were spread across the state. The Authority's first call for proposals for the use of their initial funding had been so successful that it was obvious that the resources of the Authority could not meet the demand. Mr. Veeder pointed out that some 20 per cent of the proposals for innovation research grants were biotechnology related and that the incubator facilities program could shelter biotechnology related companies as well as other technology based businesses.

The committee agreed to appoint a subcommittee consisting of the cochairmen of the study committee and Senator Royall and Representative Huskins to formulate a proposal for the short session of the General Assembly, in cooperation with the Governor and the universities. The work of that subcommittee resulted in the recommendations contained in this report.

The final meeting of the committee prior to the 1984 Short Session of the Legislature, was held on May 15, 1984. The committee received the report of its subcommittee and adopted its recommendations. It also defined the scope of its work when it begins meeting after the close of the 1984 Short Session. The section of this report which follows contains an outline of the additional work the committee will undertake at that time.

FUTURE ACTIVITIES OF THE COMMITTEE

The next phase of the committee's work, which will culminate in its report to the 1985 Session of the General Assembly, will focus primarily on the question of long term needs necessary to make North Carolina a center of excellence in biotechnology. Several important questions must be answered before the committee is in a position to make its final recommendations.

Given that the effect of biotechnology will be pervasive, and that there is economic potential in biotechnology, the committee must determine whether or not the proposals before it (Appendix F) will attract this economic development to the state. If so, will it be sufficient to justify the cost associated with such a long term plan? If a long range plan is put into effect, and it does attract economic development, how can that economic development be spread across the state so that it is not concentrated in only one or two areas?

Turning those questions around, the committee has also raised the question of what would happen if you undertook something less than a full scale comprehensive effort aimed at economic development? For example, what if you undertook an effort directed only at the specific, existing strengths in the state, such as agriculture and forestry? Finally, there is the question of what happens if you do nothing?

In order to help resolve these questions, the committee has decided to appoint an advisory committee, as suggested at its meeting on April 19, 1984. (See pages 27-28 of this report.) This advisory committee will be given a reporting date that will allow the study committee sufficient time to receive its information and make decisions for the 1985 session.

The committee must also reach final conclusions on the question of whether or not the federal guidelines for biotechnology related research undertaken with federal funds are a sufficient device, or whether there should be any laws enacted to control research. There are presently no specific statutes or guidelines for the actual development of biotechnology related products, and the committee will have to reach a conclusion on this point as well.

The committee intends to resume its meeting schedule immediately after the close of the 1984 session of the Legislature.

APPENDIX A

MEMBERS
LEGISLATIVE RESEARCH COMMISSION 1983-84

House Speaker Liston B. Ramsey Chairman	Senate President Pro Tempore W. Craig Lawing, Chairman
Representative Chris S. Barker, Jr.	Senator William N. Martin
Representative John T. Church	Senator Helen R. Marvin
Representative Bruce Ethridge	Senator William W. Staton
Representative John J. Hunt	Senator Joseph E. Thomas
Representative Margaret Tennille	Senator Russell Walker

MEMBERS
BIOTECHNOLOGY STUDY COMMITTEE

Senator William G. Hancock, Jr. Cochairman	Representative Bobby R. Ethridge Cochairman
Senator Robert M. Davis, Sr.	Representative Sam Beam
Senator Charles W. Hipps	Representative Marie Colton
Senator Robert B. Jordan, III	Representative John J. Hunt
Senator Kenneth C. Royall, Jr.	Representative J. P. Huskins
Senator William Staton	Mr. Charlie Carpenter
Dr. Wendell Allen	Dr. Frank Hart
Dr. Roy E. Morse, Sr.	Mr. James E. Gapinski
Mr. William Veeder	

Steven Rose, Committee Counsel
Jerry Batchelor, Committee Clerk

Dr. Laura Meagher, Acting Administrator,
North Carolina Biotechnology Center and
Dr. Don I. Phillips, Executive Director,
Government/University/Industry Research Roundtable,
National Academy of Sciences, formerly Director,
North Carolina Biotechnology Center, served as
technical staff to the study committee

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 1983

SENATE JOINT RESOLUTION 620*

Sponsors: Senators Hancock, Jordan.

Referred to: Rules and Operation of the Senate.

June 15, 1983

1 A JOINT RESOLUTION AUTHORIZING THE LEGISLATIVE RESEARCH
2 COMMISSION TO STUDY THE NEEDS FOR THE DEVELOPMENT OF
3 BIOTECHNOLOGY IN NORTH CAROLINA.

4 Whereas, biotechnology is a new frontier of science that
5 will lead to new products and processes worth 40 billion dollars
6 in the year 2000 and that will affect 70 percent of the GNP in 30
7 years; and

8 Whereas, biotechnology is already the basis for new
9 products in the human and animal health field and has even
10 greater potential to lead to new, valuable agriculture and
11 forestry products; and

12 Whereas, advances in biotechnology will be critical to
13 maintaining the health and vitality of the State's traditional
14 industries - agriculture and forestry - and of many of its
15 developing industries - pharmaceuticals and health care - and
16 biotechnology also will be the basis for the development of new
17 small businesses; and

18 Whereas, a strong educational, research, financial, and
19 institutional base is necessary to attract the substantial funds
20

1 now being invested in biotechnology and to nurture the
2 development of existing industry and new small businesses; and

3 Whereas, North Carolina has the potential to realize
4 economic benefits from advances in biotechnology, but the
5 competition is severe among the states to attract the investments
6 and to nurture the growth in biotechnology; and

7 Whereas, earlier concerns with the safety of
8 biotechnology research and development have decreased
9 substantially;

10 Now, therefore, be it resolved by the Senate, the House of
11 Representatives concurring:

12 Section 1. The Legislative Research Commission shall
13 review the basis of the projections that biotechnology will have
14 a pervasive impact on industries such as pharmaceuticals,
15 agriculture, forestry, chemicals, pollution control, and other
16 areas that the Commission might identify.

17 Sec. 2. The Commission shall review the development of
18 the federal guidelines for the safe conduct of biotechnology
19 research and development and the experiences of other states that
20 have addressed this issue.

21 Sec. 3. The Commission shall review the steps being
22 taken by other states to strengthen their education, research,
23 financial, and institutional resources in biotechnology.

24 Sec. 4. The Commission shall review the current status
25 and future plans of the biotechnology programs in North
26 Carolina's universities, the North Carolina Biotechnology Center,
27 North Carolina companies, the Department of Commerce, and any
28

1 other organizations concerned with nurturing the development of
2 biotechnology in the State.

3 Sec. 5. The Commission shall determine the short-term
4 and long-term needs for North Carolina to be at the forefront of
5 the technological and economic developments in the rapidly
6 advancing field of biotechnology.

7 Sec. 6. The Commission may call upon any State
8 department or agency to provide it with information pertinent to
9 its inquiry. In addition, the Commission may invite
10 representatives of private industry and universities as well as
11 experts from other states and the federal government to offer
12 pertinent testimony.

13 Sec. 7. The Commission shall appoint a Committee to
14 conduct the study outlined above. The membership of the
15 Committee shall consist of five members of the House and five
16 members of the Senate, two representatives of North Carolina
17 universities with programs in biotechnology, two officials from
18 North Carolina companies engaged in research, development, and
19 production in biotechnology, and two representatives from the
20 financial community knowledgeable concerning the investment
21 climate in biotechnology.

22 Sec. 8. The Commission shall file a report with the
23 Governor and the General Assembly no later than May 1, 1984. The
24 report shall set forth the Study Commission's findings,
25 conclusions, recommendations, and proposed legislation, if any.
26 At this time, the Commission also may request that the study be
27 continued.

28

1 Sec. 9. The Legislative Services Commission shall
2 provide professional and other staff assistance upon the request
3 of the Commission. The Commission may wish to seek additional
4 staff assistance from the North Carolina Biotechnology Center and
5 the universities. In addition, up to twenty-five thousand
6 dollars (\$25,000) of the appropriations in 1983-84 and 1984-85 to
7 the Biotechnology Center in "The New Technology Jobs Act" shall
8 be used by the Center to support this study.

9 Sec. 10. This resolution shall become effective July 1,
10 1983.

GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 1983

HOUSE JOINT RESOLUTION 1282*

Sponsors: Representative Bob Etheridge.

Referred to: Rules and Operation of the House.

June 14, 1983

1 A JOINT RESOLUTION AUTHORIZING THE LEGISLATIVE RESEARCH
2 COMMISSION TO STUDY THE NEEDS FOR THE DEVELOPMENT OF
3 BIOTECHNOLOGY IN NORTH CAROLINA.

4 Whereas, biotechnology is a new frontier of science that
5 will lead to new products and processes worth 40 billion dollars
6 in the year 2000 and that will affect 70 percent of the GNP in 30
7 years; and

8 Whereas, biotechnology is already the basis for new
9 products in the human and animal health field and has even
10 greater potential to lead to new, valuable agriculture and
11 forestry products; and

12 Whereas, advances in biotechnology will be critical to
13 maintaining the health and vitality of the State's traditional
14 industries - agriculture and forestry - and of many of its
15 developing industries - pharmaceuticals and health care - and
16 biotechnology also will be the basis for the development of new
17 small businesses; and

18 Whereas, a strong educational, research, financial, and
19 institutional base is necessary to attract the substantial funds
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1 now being invested in biotechnology and to nurture the
2 development of existing industry and new small businesses; and

3 Whereas, North Carolina has the potential to realize
4 economic benefits from advances in biotechnology, but the
5 competition is severe among the states to attract the investments
6 and to nurture the growth in biotechnology; and

7 Whereas, earlier concerns with the safety of
8 biotechnology research and development have decreased
9 substantially;

10 Now, therefore, be it resolved by the House of Representatives,
11 the Senate concurring:

12 Section 1. The Legislative Research Commission shall
13 review the basis of the projections that biotechnology will have
14 a pervasive impact on industries such as pharmaceuticals,
15 agriculture, forestry, chemicals, pollution control, and other
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9 its inquiry. In addition, the Commission may invite
10 representatives of private industry and universities as well as
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14 conduct the study outlined above. The membership of the
15 Committee shall consist of five members of the House and five
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17 universities with programs in biotechnology, two officials from
18 North Carolina companies engaged in research, development, and
19 production in biotechnology, and two representatives from the
20 financial community knowledgeable concerning the investment
21 climate in biotechnology.

22 Sec. 8. The Commission shall file a report with the
23 Governor and the General Assembly no later than May 1, 1984. The
24 report shall set forth the Study Commission's findings,
25 conclusions, recommendations, and proposed legislation, if any.
26 At this time, the Commission also may request that the study be
27 continued.

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2 provide professional and other staff assistance upon the request
3 of the Commission. The Commission may wish to seek additional
4 staff assistance from the North Carolina Biotechnology Center and
5 the universities. In addition, up to twenty-five thousand
6 dollars (\$25,000) of the appropriations in 1983-84 and 1984-85 to
7 the Biotechnology Center in "The New Technology Jobs Act" shall
8 be used by the Center to support this study.

9 Sec. 10. This resolution shall become effective July 1,
10 1983.

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GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 1983
RATIFIED BILL

CHAPTER 899
HOUSE BILL 1122

AN ACT TO CREATE THE NEW TECHNOLOGY JOBS ACT.

Whereas, unemployment rates vary considerably from one region of the State to the next; and

Whereas, the creation of more and better job opportunities for North Carolinians at all age and skill levels in all regions of the State are a top priority in relation to balanced growth considerations; and

Whereas, small businesses of all kinds, including but not limited to agriculture, aquaculture and forestry enterprises, are the primary sources of employment throughout the State and they are likely to remain the primary sources of employment in the future; and

Whereas, biotechnology is a new frontier of science that is already the basis for new products and businesses in the human and animal health field and has even greater potential to lead to new, valuable agriculture and forestry products; and

Whereas, in recognition of the importance of biotechnology to the industrial base of the State, the North Carolina Board of Science and Technology established the North Carolina Biotechnology Center to pursue opportunities in biotechnology research, education, and business development special benefit to the State; and

Whereas, the Biotechnology Center has documented that it can leverage its State funds with at least an equal additional amount from non-State sources and that it can contribute to the development of new and existing businesses and research opportunities; and

Whereas, scientific and technical advances in general flowing from research and academic institutions can be applied to the development of existing and new small businesses throughout the State; and

Whereas, principal growth in employment has come from the introduction of new technology; and

Whereas, adequate capital and affordable space for the research activities of existing and new small businesses are key ingredients to the development of new and existing small businesses; and

Whereas, partnerships between State and local government, financial institutions, business, labor, and research and academic institutions provide the most effective means for utilizing technological resources to create new jobs throughout the State; Now, therefore,

The General Assembly of North Carolina enacts:

Section 1. G.S. 143B-433 is amended by inserting a new subsection to read:

"(22) The North Carolina Technological Development Authority,".

Sec. 2. Article 10 of Chapter 143B of the General Statutes is amended by adding a new Part to read:

"Part 12. North Carolina Technological Development Authority.

"§ 143B-471. Creation of Authority.--There is hereby created the North Carolina Technological Development Authority, to increase the rate at which new jobs are created in all regions of the State, by stimulating the development of existing and new small businesses. The Authority shall be administratively located within the Department of Commerce, but shall exercise its powers independently of the head of that department, as if it had been transferred to the Department of Commerce by a Type II transfer as defined in G.S. 143A-6(b).

"§ 143B-471.1. Composition of Authority.--(a) The Authority shall be governed by a board composed of 12 members, eight of whom shall be appointed by the Governor, two of whom shall be appointed by the General Assembly upon the recommendation of the President of the Senate under G.S. 120-121, and two of whom shall be appointed by the General Assembly upon the recommendation of the Speaker of the House of Representatives in accordance with G.S. 120-121. Consideration should be given to the appointment of persons, including minorities and females, with technical expertise as well as experience in entrepreneurial business development and capital formation.

(b) Members shall serve four-year terms effective July 1, 1983, and quadrennially thereafter, except that the two members appointed by the General Assembly upon the recommendation of the Speaker of the House of Representatives shall serve for two-year terms effective July 1, 1983, and biennially thereafter. No person appointed to a four-year term shall serve more than two consecutive terms.

(c) Vacancies shall be filled by the Governor to serve the remainder of the unexpired term, except that vacancies in appointments made by the General Assembly shall be filled in accordance with G.S. 120-122.

"§ 143B-471.2. Officers; meetings.--(a) The Governor shall appoint from the members of the Authority a chairman. The Authority shall elect from among its members a Vice-Chairman and shall elect a secretary.

(b) The Authority shall meet at the call of the Chairman, upon the written call of the majority of its members or upon resolution of the Authority.

(c) A quorum shall consist of seven members of the Authority.

"§ 143B-471.3. Compensation.--Members of the Authority shall receive per diem and necessary travel and subsistence expense in accordance with G.S. 138-5.

"§ 143B-471.3A. Powers.--In order to enable it to carry out the purposes of this Part, the Authority may:

(1) Exercise the powers granted corporations under G.S. 55-17;

(2) Employ an Executive Director, whose salary shall be set by the Governor and the Authority, after consultation with the Advisory Budget Commission. The Authority may employ such other professional staff and clerical and secretarial staff as it deems necessary within the funds available to it. The salaries of such other personnel shall be set under the State Personnel Act;

(3) Establish an office for the transaction of its business at Raleigh;

(4) Apply for and accept grants of money from the State of North Carolina, or any political subdivision thereof, from the United States, or from any person, corporation, foundation, trust, or business or from any foreign government for any of the purposes authorized by this Part;

(5) Establish and administer the incubator facilities program;

(6) Administer the North Carolina Innovation Research Fund; and

(7) Adopt reasonable rules to effectuate the purposes of this Part.

"§ 143B-471.4. Incubator facilities program.--(a) The Authority shall establish one or more incubator facilities within the State. An incubator facility is a building or buildings that provides space and support services for small businesses concerns which are beginning. 'Small business concern' has the same meaning as that contained in Chapter 14A of Title 15, United States Code, and regulations promulgated under it.

(b) The Authority shall select sites for incubator facilities. The Authority in selecting sites shall evaluate areas for potential sites using the following criteria but is not limited to them:

- (1) the unemployment rate,
- (2) the need for industrial and economic diversification and development,
- (3) the interest by the locality in the establishment of an incubator facility in the area as manifested by grants from public and private sources and cooperation agreements between local government, business, labor and educational institutions demonstrating the probability of the success of the incubator facility.

(c) The Authority may make one-time grants to establish incubator facilities. A grant may not exceed two hundred thousand dollars (\$200,000). Local government and interests must at least equal in cash or real estate value any grant made by the Authority; provided, however, that contributions by State agencies may not be included in the matching grant.

(d) Only nonprofit corporations which are affiliated with local universities, colleges, community colleges or technical institutes or combinations thereof to advance the educational and research programs of these institutions shall be eligible to receive a grant from the Authority. Pursuant to rules adopted by the Authority, the corporation shall:

- (1) manage and maintain the incubator facility,
- (2) develop a mechanism to provide technical, management and entrepreneurial expertise to resident small business concerns and to small business concerns throughout the area, and
- (3) abide by rules adopted by the Authority.

(e) The incubator facility and any improvements shall be owned by the State but may be leased to the corporation. Small business concern residents of the facility may be provided secretarial and other support facilities and utilities for which

the corporation may charge them a part or all of the cost. No small business concern may remain in the facility for more than two years. Notwithstanding any other provision of law, the State shall not be liable for any act or failure to act of any organization granted funds under this Part, or any small business concern benefiting from the incubator facilities program.

"§ 143B-471.5. North Carolina Innovation Research Fund.--(a) The North Carolina Innovation Research Fund is hereby created to provide equity financing for the research activities of new and existing small business concerns in various regions of the State, including agriculture, aquaculture and forestry enterprises. This financing is designed to enable small business concerns to acquire technical and management assistance and otherwise to conduct research leading to new or improved product or service development.

(b) The Fund will take an equity position in contracting concerns through the purchase of stock, the receipt of royalties, or other equity instruments.

(c) The Fund will consist of appropriations from the State; monies derived from federal, local governments and private grants; receipt of royalties and sale of equities.

(d) Awards per research project shall not exceed fifty thousand dollars (\$50,000) per fiscal year. Awards will be limited to concerns physically located in North Carolina, but the awards shall not be limited to incubator-affiliated projects.

(e) To protect its investments, the Authority shall make development agreements with contracting concerns, to ensure proper use of Fund awards and the receipt of royalties, where appropriate. Development agreements shall assign all rights to abandoned projects to the Authority.

(f) Any funds received through the receipt of royalties, dividends, or the sale of equity instruments shall be deposited in the Fund and are available to the Authority for use under this Part."

Sec. 3. G.S. 120-123 is amended by adding a new subdivision to read:

"(6a) The North Carolina Technological Development Authority as created by G.S. 143B-471."

Sec. 4. Of the funds appropriated from the General Fund to the Department of Commerce in Section 2 of Chapter 761 of the 1983 Session Laws, for fiscal year 1983-84 the sum of five hundred thousand dollars (\$500,000) and for fiscal year 1984-85 the sum of five hundred fifty thousand dollars (\$550,000) is designated for the purposes of the North Carolina Technological Development Authority. Of the funds so appropriated for fiscal year 1983-84, the sum of two hundred twenty-five thousand dollars (\$225,000) is available only for the North Carolina Innovation Research Fund, the sum of two hundred thousand dollars (\$200,000) is available only for grants to incubator facilities, and the sum of seventy-five thousand dollars (\$75,000) is available only for the operation of the Technological Development Authority. Of the funds appropriated for fiscal year 1984-85, the sum of two hundred fifty thousand dollars (\$250,000) is available only for the North Carolina Innovation Research Fund, the sum of two hundred thousand dollars (\$200,000) is available only for grants

to incubator facilities, and the sum of one hundred thousand dollars (\$100,000) is available for the operation of the Technological Development Authority.

Sec. 5. Of the funds appropriated from the General Fund to the Department of Commerce in Section 2 of Chapter 761 of the 1983 Session Laws, for fiscal year 1983-84 the sum of four hundred eighty-five thousand dollars (\$485,000) and for fiscal year 1984-85 the sum of four hundred ninety thousand dollars (\$490,000) is designated for the purposes of the Biotechnology Center, provided that funds for fiscal year 1984-85 shall not be released unless the Biotechnology Center has raised at least five hundred thousand dollars (\$500,000) in non-State funds during the period beginning with the date of ratification of this act and ending on June 30, 1984; provided further that these appropriations shall not become part of the continuation budget for 1985-87 unless the Biotechnology Center has raised a total of one million dollars (\$1,000,000) in non-State funds by December 31, 1984.

Sec. 6. Of the funds appropriated from the General Fund to the Department of Commerce in Section 2 of Chapter 761 of the 1983 Session Laws, the sum of fifteen thousand dollars (\$15,000) in fiscal year 1983-84 and the sum of ten thousand dollars (\$10,000) in fiscal year 1984-85 is transferred to the Legislative Research Commission to conduct a study of the field of biotechnology.

Sec. 7. This act is effective upon ratification.

In the General Assembly read three times and ratified, this the 21st day of July, 1983.

JAMES C. GREEN

James C. Green

President of the Senate

LISTON B. RAMSEY

Liston B. Ramsey

Speaker of the House of Representatives

STATE OF NORTH CAROLINA
LEGISLATIVE RESEARCH COMMISSION
STATE LEGISLATIVE BUILDING
RALEIGH 27611



January 27, 1984

MEMORANDUM

TO: Members of the Biotechnology Study Committee
FROM: Steven Rose, Committee Counsel 
RE: Summary of ideas and concerns expressed at meeting of
December 14 and 15, 1983

Introduction

The first meeting was structured to educate the study committee on the subject of biotechnology. The speakers explained what it is, talked about the potential for the future, and were given an opportunity to express initial ideas and concerns on the subject to the committee. Although the meeting was lengthy and covered a wide range of ideas, it was, nevertheless, an overview and it is expected that some aspects of what was heard by the committee will be earmarked for further study. It is the purpose of this memorandum to pull these ideas and concerns together in order to assist the committee in determining what it wants to look at in depth.

What Is Biotechnology?

Biotechnology is not a new or separate scientific discipline. One way of looking at biotechnology is that it is a collection of new techniques, which make possible novel extensions and combinations of existing scientific disciplines, centering on biology, and new industrial applications. The understanding of the structure of DNA, combined with the ability to manipulate genes and to reproduce the results of that manipulation, is what biotechnology is all about. These new techniques will revolutionize many sciences and manufacturing processes and will have a pervasive effect on everyone's life in the very near future.

Biotechnology will affect the areas of food production and processing (plants and animals, on land and in the water), marine biology, forestry, fiber, medicine, chemicals, mining, pollution control and waste management. A few examples which were given at the meeting will suffice to show the revolutionary aspects of the changes that will be coming. For instance, virtually all chemicals are presently petroleum based. Biotechnology will change the way chemicals are produced in the future so that many will no longer be petroleum based. A biological basis for chemical production will vastly reduce this country's, and the world's, dependence on oil. In the area of food plant production, there will be a shift away from chemicals to control pests and disease. Eventually, resistant strains will be quickly identified and will be reproduced using cloning techniques. In medicine, the committee heard

about the "magic bullet" technique of treatment. This ability to identify those cells which are responsible for an illness and create treatments which will seek out and treat only those cells holds the promise for cures for many forms of cancer, as well as other diseases.

There were many other examples of such things to come given over the course of the two day meeting. The point was that changes are coming, and the future will be here sooner than we might think. These changes hold the prospect of affecting the lives of everyone in the world.

In the area of safety and control of biotechnology research, the initiative was originally taken by the scientific community itself and resulted in comprehensive National Institute of Health guidelines on recombinant DNA research. These include provisions for individual approval of certain kinds of experiments. Although they are only applicable to federally funded projects, they are generally accepted as policy models by private concerns and by other countries. A few states and local governments around the country have adopted the NIH guidelines as law, allowing them to exercise control over the private sector.

The Economic Potential of Biotechnology for North Carolina

It was obvious from the presentations that the big companies are very much aware of the future impact of biotechnology, especially those whose businesses will be changed by it, such as chemical companies. Small companies are becoming increasingly involved, as well. It was also obvious that the

academic institutions of the state are very much aware of the impact and are already well on their way in terms of being substantially involved in biotechnology.

The fact that biotechnology based sciences will have such a pervasive influence on our lives, means there is high economic potential to be exploited. But some geographic areas will benefit more from it in terms of increased jobs and plant investment than others.

One of the charges of this committee is to determine how this economic benefit can be brought to North Carolina. One of our speakers, Dr. Stuart Bondurant, Dean of the Medical School at UNC-CH, said that in order to attract the biotechnology related companies to our state, it is important that we rate an "A" grade as a biotechnology center. Presently, he rated North Carolina as a strong "B." However, according to Dr. Bondurant, there are presently only two centers for biotechnology in the country that rate an "A," those being the San Francisco - Palo Alto area and the Boston area. So there is still time for North Carolina to achieve that higher grade. Just what do these companies look for in choosing a location, or putting it another way, how can we earn that "A" grade?

Various speakers indicated that the following were factors which would influence companies to locate in North Carolina:

1. Excellent universities, public and private.
2. Accessibility to industry of the university research bases.

3. A demonstrated interest in biotechnology by the state government.
4. The existence of a facility like the Research Triangle Park.
5. The presence of other biotechnology firms (the magnet effect).
6. A productive labor pool willing to be trained.
7. Available skills training.

North Carolina has a head start over most other states in all of these areas. However, there are stirrings in this field all over the world. So one question becomes, how can we capitalize on what we already have, thereby maintaining this head start?

Specific Points and Concerns.

The following is a list of specific points, needs, and concerns raised by the speakers. Some were raised by only one speaker, while others were repeated many times.

I. University related institutional needs.

- A. Strong and continuing financial support for basic research. (Researchers must be able to depend on long-term financial support for long-term research projects.)
- B. More research space.
- C. Proper research equipment.
- D. Legislature needs to be attentive to requests for money related to biotechnology research.
- E. Expansion of the "small grants program" to

support innovative but high risk research.

- F. Redirection of some traditional research areas.
- G. Facilitation of multi-disciplinary research.
- H. Encouragement of cooperation between academic institutions.

II. University "people" concerns.

- A. The need to attract world class researchers.
- B. Stopping the "brain drain" of scientists and technicians from the universities.
- C. The need for great teachers to train those researchers and technicians who will work in biotechnology.
- D. Providing money for better salaries to help accomplish the preceding three.
- E. Creating an environment which supports and encourages people to get their ideas into actual production.

III. Relationships with industry.

(Virtually all of the items under this section deal with public institutions.)

- A. Possible changes in patent and licensing arrangements between universities and industry.
- B. Exploration of royalty arrangements between universities and industry.
- C. Incentives for individual researchers, such as royalties, consulting opportunities, or other monetary relationships with industry.

IV. Other university related points.

- A. Do we need new programs or a way to facilitate the blending of existing programs?
- B. Stipends and other support for graduate students.
- C. Exploration of state restrictions on salary enhancement.
- D. Ear-marking of biotechnology related funds by the legislature.
- E. Inclusion of the private institutions in the state's biotechnology efforts.

V. Public schools and community colleges.

- A. Create biotechnology literacy for the general public.
- B. Provide good teachers and proper equipment to train those who will be the workers in biotechnology related industries.
- C. Insure that those teachers remain in the public school and community college systems and are not drained away to industry.
- D. Begin the educational focus on biotechnology in the junior high schools.

VI. Private sector development.

- A. Find people for jobs already here.
- B. Providing research and other support facilities for industry. (Some of these may be of the incubator type, but some of these may interface with existing and larger corporations.)

- C. Seed money for start-up capital.
- D. Insuring that North Carolina is perceived as a biotechnology center.
- E. Explore creating a structure similar to the Microelectronics Center.

VII. Safety and control.

- A. Should the State regulate the safety and control aspects of biotechnology research and production?
- B. If so, what should those controls be?

VIII. Miscellaneous points.

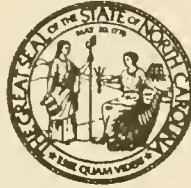
- A. What will the effect of biotechnology be on the family farm?
- B. How can we encourage cooperation between state government resources, academia and industry?
- C. How can we facilitate the movement from research to actual application?
- D. What might the future structure and direction of the Biotechnology Center or the Technology Development Authority be?
- E. How might other state agencies promote development of North Carolina as a biotechnology center?

The Role of the Legislature

One observation which must be made is that while many of the items listed above might be influenced by legislative

action, many cannot. It is important that the committee keep sight of this as it defines what its work will be.

STATE OF NORTH CAROLINA
LEGISLATIVE RESEARCH COMMISSION
STATE LEGISLATIVE BUILDING
RALEIGH 27611



February 17, 1984

MEMORANDUM

TO: Members of the Biotechnology Study Committee

FROM: Steven Rose and Laura Meagher

RE: Staff Proposals For A Comprehensive Approach to the Development of
Biotechnology in North Carolina

These staff proposals are prepared in response to the request of the Legislative Study Committee on Biotechnology on January 27, 1984, for an initial overview of an initiative that might be taken by North Carolina if it is to achieve "A" status nationwide in biotechnology. The plan outlined here was prepared in light of informal input from Frank Armstrong, North Carolina State University; Marshall Edgell, University of North Carolina at Chapel Hill; Quentin Lindsey, Office of the Governor; Don Phillips, formerly North Carolina Biotechnology Center; individuals from Duke University administration, and other individuals and institutions. As a draft, it is intended to reflect in a preliminary fashion many of the concerns expressed by various individuals, institutions, and organizations; but it is not yet in any sense a "formally" approved document and modifications would therefore be expected. It is hoped, however, that this document will respond to the Committee's request by providing a framework with which to envision viable possibilities for a comprehensive approach to the development of biotechnology in North Carolina.

I. RATIONALE

A. Introduction

North Carolina has been called a "Solid B" in biotechnology; at this moment it enjoys a headstart among states seeking to develop their biotechnology capabilities in strategies for economic development. North Carolina's present status rests upon investments already made by the state in its universities, the North Carolina Biotechnology Center, and its relationships with industry in the Research Triangle Park and elsewhere. In order that these investments be utilized to their maximum potential, particularly in light of the immense promise of biotechnology, the Legislative Study Committee has asked for an outline of possible steps which the state might take to move from a B to an A. This draft document has been prepared to provide one possible comprehensive view of additional resources needed to move the state ahead to that leadership position.

Biotechnology itself is so multi-faceted, and North Carolina's capabilities so multi-dimensional, that choosing the best form to be taken by this additional effort is a complicated endeavor. For this reason, at this point in the deliberative process, it seems appropriate to make very clear the nature of this document, what it is and what it is not. It is not a final, formal document which has gone through official channels of approval. Instead, it is a draft which represents an attempt to synthesize in a preliminary fashion input and concerns from public and private universities, the private sector, and state government. Although it is hoped that this document is in fact reflective of varied needs, it is equally expected that several iterations of revision will take place. At

present, in short, this draft is a "talking piece". The aim of this document is three-fold (1) To present in one document an overall sense of the necessarily comprehensive nature of a statewide biotechnology effort; (2) To provide information on a framework of resources that may be needed to move North Carolina to an "A" in biotechnology; (3) To present an overview of possible steps to be taken, along with order of magnitude costs, over the next five years.

In this draft, a brief overview of very broad, general goals will be followed by an outline of more specific, attainable objectives which will address those goals, and then by an outline of resources needed to meet those objectives. The draft will conclude with an outline of specific needs, over the next five years, that the Legislature may wish to consider in its deliberations. The intent is to move progressively from overall goals through a coordinated framework of concerns to practical steps which can be taken to further those goals. Again, possibilities put forward here are suggestions only, yet is hoped that, at the least, these suggestions will serve to highlight the sorts of decisions that need to be made in the near future if North Carolina is to become an internationally recognized leader in biotechnology.

B. Goals

1. Industrial development in North Carolina

Clearly, a broad overarching goal for any state initiative is the improvement of life in North Carolina, and one key to this is a healthy economy. Industrial development in biotechnology could, over time, contribute significantly to the economic growth of North Carolina. This development could

take the form of the location in the state of research and development and/or production facilities of established national firms, as well as of the emergence of small, entrepreneurial company activity in biotechnology. North Carolina has already embarked upon a route of seeking industrial development. First, the existence of the Research Triangle Park demonstrates an openness to industry-university interactions. Individual universities have reexamined patent, consulting, and technology transfer policies, or are in the process of doing so. The state's highly visible and significant investment in the Microelectronics Center of North Carolina and to a lesser degree, the North Carolina Biotechnology Center, have signalled a commitment in high technology to the national private sector. In addition, experimental efforts are now emerging which are directed toward the encouragement of entrepreneurial activity. The Technology Development Authority established by the Legislature in 1983 is a prime example of this sort of effort.

The impact of biotechnology is already being felt in a variety of industries, and the economic implications for the future are profound. Both through its research community and through industrial development, North Carolina has or could have an opportunity to address some further fundamental, far-reaching goals through biotechnology. Participation in achieving these goals can earn North Carolina a leadership role.

2. Improved livestock, crop, tree and aquaculture production.

These are goals of obvious relevance to a state as active in, and dependent upon, these areas as is North Carolina.

3. Improved health through medicine and pharmaceuticals.

Documentation is already emerging for the ability of biotechnology to improve, sometimes "miraculously", present capabilities in medicine and

pharmaceutical. Whether through "magic bullets" of medication, diagnostic kits or increased understanding of the genetic basis of diseases, biotechnology plays a role in this established area of emphasis in North Carolina. Obviously, improved medical capabilities leads to improved quality of life for North Carolina. Several other long-range goals of universal interest have roles still open for North Carolina to play.

4. Production of useful chemicals.

The improvement of the capabilities of the various chemical industries, for instance, could lead to decreased dependence on petroleum. Biotechnology could have a significant impact in terms of feedstock production, fermentation processes, enzyme-based processes, and synthesis of new materials.

5. Protection of the environment.

Effective use of renewable resources, including biomass, could apply biotechnology to energy production as well as to waste treatment and utilization and detoxification of poisonous wastes.

6. Marriage of biotechnology and microelectronics.

The merging of biotechnology with microelectronics in the future production of sensors and "biochips" is a long-range goal currently receiving much attention worldwide. North Carolina has an unusual combination of capabilities in these two areas to be merged.

7. New frontiers in basic research.

Finally, perhaps the single most far-reaching goal is improved capabilities in basic research. If key areas of biology, such as molecular genetics, gene regulation, cell differentiation and development, and so on are actively pursued, their potential is unpredictable, but may be revolutionary in

scope. The most unexpected areas of "pure" research may lead to discoveries of commercial relevance. After all, biotechnology with all its vast industrial impact, springs from findings of the most basic of research. North Carolina has already invested heavily in high quality education and research universities; the complementary strengths of its various public and private institutions give it a unique breadth of capabilities. This unusual breadth can serve the state well in its efforts to attract high technology industrial development and the investment can be returned many-fold.

These goals are broad and far-reaching ones. As such, they demand multifaceted, interwoven strategies for their attainment. Not only must conceptual breakthroughs be achieved, at the lab bench, for instance, but also, the new ideas and techniques must be moved along out into the realm of practical development. Industry--whether in the form of established companies or of entrepreneurial start-up companies--must be able to pick up and move with these new ideas and techniques. Appropriate financing, often venture capital, must be available in the early stages of development. Widespread perception of North Carolina as a center for biotechnology activity is likely to draw additional resources to each stage of the process, whether through recruitment of top quality research faculty, or attraction of financial investment. After all, existing "A" areas in biotechnology have developed in areas adjacent to multiple universities of national reputation, and have involved faculty from those universities in significant entrepreneurial activity.

What is critical to remember is that no one element can stand alone; all must be closely interwoven for the necessary synergistic effect to occur. Linkages are vital. These may take the form of linkages across scientific

disciplines, because biotechnology is opening up questions that require a variety of perspectives and expertise. Connections between research and commercial development are equally necessary. There must be some degree of accessibility at which the universities operate, such that results of basic research can be transformed into commercial products and processes. At the same time, the private sector bears responsibilities of its own in what must, if it is to succeed, be a two-way partnership. Seed, start up and venture capital, and other forms of financing, must be linked to appropriate efforts. In short, any successful statewide effort in biotechnology must be comprehensive; the establishment of not only strong individual "components" of a biotechnology strategy, but also an open yet helpful network among the components could make North Carolina unique.

The above-mentioned are large-scale, fundamental goals. They constitute the overall context or rationale for involvement by the state in biotechnology, and are thus important to bear in mind. These broad goals can, however, be distilled into more specific, more attainable "objectives", which may be more useful as foci in this action-oriented document.

II. OBJECTIVES TO BE MET IF NORTH CAROLINA
IS TO BE TRANSFORMED INTO A LEADERSHIP ROLE

Introduction

A substantive North Carolina initiative in biotechnology can be seen as addressing three primary objectives: (1) new agricultural, biomedical, and industrial development and investment in North Carolina, (2) creation of new knowledge and techniques (education and research), and (3) enhancement of North Carolina's image as a national leader in biotechnology.

These objectives are not, of course, completely separable from each other, nor should they be. The extent to which each objective is met can only serve to strengthen the response to the others. For example, research conducted at the frontiers of one field within biotechnology could so enhance North Carolina's image as to attract the establishment in the state of an industrial facility involved in the practical application of that field. In turn, this facility might give rise to a spin-off entrepreneurial company in yet another field of biotechnology, perhaps directly or perhaps only tangentially related to the original research. The highly visible presence of this sort of activity could encourage other companies to become established in North Carolina (the "snowball effect"). Those companies might themselves hire consultants in North Carolina universities or participate in University/NCBC/Industry collaborative research centers, and thus the interweaving could progress indefinitely.

A. Objective 1: New Agricultural, Biomedical and Industrial Development and Investment

New industrial development and investment in the state can take several forms: (1) Established firms may choose to locate biotechnology research

facilities and/or production facilities in the state. Substantial research facilities, such as those of CIBA-GEIGY, may in some cases come first, attracted to the high quality of university research capabilities in the state. Later, as biotechnology matures and industrial applications become realities, production facilities may be located in the same state as the research facilities, although not necessarily in the same city. (2) Small to medium-sized companies may incorporate biotechnology into their business plans if they can perceive both advantages to biotechnology in general and ready access to biotechnology capabilities. (3) Finally, if university scientists and engineers operate in the midst of a supportive infrastructure, they may themselves initiate small entrepreneurial companies. Venture capital investment could thus become an increasingly vital element of the overall North Carolina picture.

B. Objective 2: Creation of New Knowledge and Techniques Which Will Lead to Developments in All Fields.

North Carolina could build upon its already existing excellence in research to become a leader in biotechnology. The University research strength needs to be equivalent to the very best already present in existing centers (i.e. Boston, and the Palo Alto, California areas.) Multiple university-centers of strength have been the major foci of biotechnology to date. Importantly, each of North Carolina's primary research universities--public and private--has particular strengths; taken as a total, the university research strength could be unmatched in the U. S. Such complementarity is particularly important when research problems are as interdisciplinary as they are in biotechnology. To the extent that collaborative efforts actually take place and a true community grows, the

total force of biotechnology in North Carolina could be significantly more than the sum of its parts. This is one "edge" over other states, that North Carolina currently possesses and could deliberately develop. The spectrum of training capabilities present in the state already makes possible biotechnology education at the undergraduate, masters, and doctoral level. The Community College System is currently investigating the feasibility of offering biotechnology training, providing skilled labor at yet another level.

C. Objective 3: Enhancement of North Carolina's Position as a Home for Biotechnology Enterprise

North Carolina's national image can be enhanced simultaneously on several levels. If North Carolina becomes highly visible at the forefront of research in several biotechnology-related fields, this will demonstrate quite clearly the essential credibility of a state initiative. A leadership role in training at several levels should be demonstrated not only by educational institutions but also by industrial firms. If North Carolina can prove sufficiently attractive to cause several established firms to set up research and development or production facilities here, each firm will add to the state's national image as a natural home for biotechnology industry. Similarly, each reasonably successful start-up company can demonstrate a climate conducive to entrepreneurial activity. It is vital that all these activities, as they take place, be made highly visible on the national scene. To the extent that they are perceived not as chance occurrences, but as elements co-existing in a synergistic, multifaceted statewide initiative, then each activity will strengthen development of other activities through enhancement of North Carolina's overall image.

III. TYPES OF RESOURCES NEEDED TO MEET OBJECTIVES

Introduction

To achieve these objectives, certain resources are needed. These fall generally into three categories: People, Supportive Infrastructures, and Facilities. As mentioned above, the primary objectives for a statewide initiative overlap extensively. So, too, do these resources. In many cases a resource--such as a critical mass of world class researchers--will prove useful in the attainment of all three of the objectives.

A. People

Ultimately, the quality of our scientific enterprise is determined by our scientists and engineers and the vigor of their ideas and activities. Thus, "people" comprise the essential resource upon which the level of biotechnology development in the state will depend.

1. Top Quality Individuals: Recruitment and Maintenance

Resources include the development of a broad base of top quality individuals, to be recruited and substained. A major component of this is the deliberate recruitment of an appropriate number of "superstars", or world class scientists. Estimates of current North Carolina scientists in biotechnology who could now be assigned this standing tend to range from 5 to 15 (definitions are difficult). Estimates of the critical mass necessary fall more in the range of 20-40 minimum. Questions of distribution among fields and institutions may solve themselves naturally; the key idea seems to be one of critical mass in the state as a whole. Not only will this place North Carolina at the forefront of

research quite dramatically, it will attract industry's attention on a sound and lasting basis--not as a "gimmick" but as a sustained and substantial investment.

In addition to the superstars, a number of young scientists and engineers of the highest caliber is necessary. The presence of a stimulating level of potential collaboration will not only attract and retain the superstars, but will also produce good science, interest industry, and provide excellent training opportunities. With these younger cutting-edge researchers complementing the world-class individuals, outstanding graduate students and postdoctoral fellows will be all the more readily attracted. Furthermore, a "pool" is thus created from which world-class researchers of the future can be generated as products of North Carolina. Generally, this infrastructure allows room for diversity in expertise, research pathways explored, new techniques cultivated, and direction of research into new areas of commercial application. Perhaps a useful rule of thumb is that two to three young but excellent researchers should be added to the research pool for every one established world class scientist or engineer. Such clusters can be deliberately constructed to provide concentrations of expertise in a variety of focussed areas. The rationale is that four scientists added to the existing strength in a particular area of focus should stand a very good chance of creating a national center of excellence here in North Carolina. Taken together, this can lead to a concentration of strengths second to no other state.

2. Top Quality Labor Supply

A top quality "labor supply", resulting from the training opportunities in the state, could include a pool of bachelor and masters and Ph.D. level individuals who could be available to a growing industrial need in

the state. Significant funding for postdoctoral and graduate student support could contribute to this objective by (a) attracting top quality students and Ph.D.'s to North Carolina, some number of which may join activities in the state; (b) enriching the level of programs now ongoing; and (c) alerting industry and others on a national level that North Carolina is making a serious commitment to biotechnology. Trained-- and therefore employable--undergraduates who are familiar with the techniques and subject matter of the new technology should prove an asset to the state. Course support will enable top quality students at all levels to be trained at the forefront of knowledge, with updated equipment and supplies. Less directly, community college and K-12 education will prepare more individuals for (a) industrial jobs in biotechnology, and (b) informed public awareness of potential challenges and opportunities afforded by biotechnology.

B. Supportive Infrastructures

1. Supportive policies: institutional

Supportive policies on an institutional level are necessary if top quality people present in and recruited to the state are to be retained. As one example, the attraction of a superstar to the state is not effective if he or she becomes frustrated by the working environment, and leaves--or simply becomes less productive--after only a short stay in North Carolina. To attract and maintain top quality people--both superstar and solid high caliber individuals, supportive policies related to such concerns as patents, overhead, professional opportunities, consulting, and equipment access, should expedite creativity, rather than stifle it. Each institution, including UNC GA is now working through these points, and many committees have been appointed; but, of course,

pertinent changes must be "felt" by the working scientist in order to be effective.

2. Supportive structures for entrepreneurial activity

In a similar vein, extension of supportive structures to entrepreneurial activity encourages a sense of creativity and "possibilities" that will be attractive to many academics of top quality. The lure of new challenges as well as the opportunity to gain additional income are attractive to many academics, and has recently become acceptable in biology as it has traditionally been in engineering. The benefit of such infrastructures does not extend merely to academics. Accessibility to business management advice, case history "cook-books", seed capital and space for start-up ventures are obviously of direct importance to the vitality of entrepreneurial activity in North Carolina. Statistics indicate that small businesses can provide a disproportionately high number of jobs. The federal Small Business Innovative Research Act has directed the set-aside of research funds for innovative research and development by small commercial firms. Some of this funding may be allocated to biotechnology. In North Carolina, in addition to the Technological Development Authority, a Council for Entrepreneurial Development has been organized by private sector firms. Encouragement of entrepreneurial activity in general can lead to a certain momentum, increasing the probability that more companies will arise in biotechnology.

3. Means of Mobilizing Resources Around Areas With Potential for Development in North Carolina

Means of mobilizing resources form a critical component of a broad supportive infrastructure. As the word "mobilizing" would indicate, these are

mechanisms for facilitating the imperatives of the North Carolina effort. For example, the more quickly and effectively the findings of basic research labs are moved into the development of applications, the more successful North Carolina will become at competition nationwide in the commercialization of biotechnology. The North Carolina Biotechnology Center has already had experience in bringing individuals together in unusual collaborative research efforts, stimulating conferences, fellowship programs, and other joint efforts among institutions. Furthermore, initial attempts have been made, and must be expanded, to transfer research into practical reality. For instance, the North Carolina Biotechnology Center is collaborating with the Research Triangle Institute to test the application of commercialization methodology to new biotechnology advances.

Experimental efforts such as the Monoclonal Lymphocyte Technology Center, need to be continued. In this case, researchers from several North Carolina universities, the North Carolina Biotechnology Center, National Science Foundation, as intended, 5 to 20 industries will join in a Cooperative University/Industry Research Center. Similarly, the North Carolina Biotechnology Center acts as a common contact point for venture capital, entrepreneurs, and others interested in developing university/industry relations. Under the New Technology Jobs Bill, which provides the North Carolina Biotechnology Center with its current funding, the Technological Development Authority was also established. With further development and expansion, this is an institution which will implement seed and start-up capital, incubator facilities, and other means of stimulating small business development and spin-offs from research. Thus it can serve as an additional means for stimulating entrepreneurial ventures throughout

the state. The North Carolina Biotechnology Center itself, in addition to its focussed work with entrepreneurs and industry generally, works with public and private universities in bridging the span between basic and development work so that ultimately all communities will have a vital stake in local agricultural, biomedical, and industrial development throughout the state.

For the overall synergistic possibilities of the state to bear fruit, in short, there must be room for a "catalyst", a forger of linkages, an organizational entity, in short, that is able to experiment. Effective ways of mobilizing resources will be varied; flexibility is demanded if a truly multifaceted interwoven initiative in North Carolina is to grow. In order to gain the maximum yield possible from the strengths of the universities -- both public and private -- within the state, there needs to be an organization that brings individuals from the institutions together to work on common objectives. Such joint activities have been and can continue to be effective at lowering the natural barriers interfering with institutional collaboration. Cooperative efforts between universities and industry can also take many forms, and can be very successful if appropriately approached. A competitive program which would fund biotechnology research proposals submitted jointly by university and industry researchers in the state, for instance, might be one approach to fostering work based on mutual interactions and trust. Other approaches could also be tried, all with a view of enhancing positive and appropriate relationships.

C. Facilities

Finally, facilities will of necessity play an important role in North Carolina's establishment in a leadership position. Without adequate,

up-to-date, state of the art equipment, research and training will be seriously handicapped.

1. Pilot Plant R&D facilities

Perhaps the outstanding "need" as far as specific facilities are concerned is a need felt nationwide: the lack of hardware which can be used in R&D for fermentation and biological processing in general. The national need for research and expertise in bioprocess engineering and scale-up is emphasized in the Office of Technology Assessment's Commercial Biotechnology, An International Analysis, 1984; a niche is currently open for leaders in this field to become established. A pilot plant which can be used in analysis of the production aspects of biotechnology by research scientists and engineers at North Carolina institutions, by industrial firms, and by start-up companies would have widespread use, it would be highly attractive to individuals in all these spheres of endeavor, and would allow North Carolina to forge ahead in an area of current national weakness. Furthermore, establishment of such facilities would in some form declare more strongly than mere words could ever do, that North Carolina is committed to the practical realities of biotechnology.

2. Research Center

A Research Center which serves as an incubator facility for biotechnology could provide another practical dimension to a well-rounded biotechnology initiative. University researchers, other entrepreneurs and even established firms moving tentatively into areas new to them, could make use of facilities wherein basic ideas are turned into development opportunities. This addresses the gap which currently exists between innovative "ideas" springing from basic research and a prototype product convincing to investors.

3. Space for Research

Another sort of needed facility is the provision of necessary space for research to be conducted by all the scientists and engineers that the state hopes to recruit. Top caliber people will not come to a situation where excellent but full laboratory conditions compromise their ability to conduct cutting edge research. In this case, additional research space is likely to be needed at all participating research institutions, to some degree.

4. Computer network

A facility that could help to draw researchers together, across disciplinary and institutional boundaries, would be a common computer network, an electronic "mail system" with which researchers throughout the state could communicate almost instantaneously about fresh data, questions, or access to resources.

5. Specialized R&D equipment capabilities

Finally, it would be helpful to researchers in the state to have available certain specialized R&D equipment capabilities. Certain expensive, highly sophisticated equipment items such as some NMRs or crystallography equipment, for instance, might be shared.

Conclusion

Inasmuch as they all contribute to the caliber of North Carolina research, training, and commercial development capabilities, the preceding resources will serve to enhance North Carolina's image. More directly, the hosting of national or international scientific meetings, in appropriate conference facilities, will call attention to the level of activity in North Carolina. So, too, will

substantive opportunities for universities, government, industry scientists and others involved in biotechnology on the national level to interact. The same mechanisms which mobilize resources in North Carolina may serve to heighten national awareness of the unique character of North Carolina's initiative.

IV. SPECIFIC NEEDS FOR CAPABILITIES TO BE PRESENT IN THE STATE BY 1989
(these are in addition to resources already existing in the state).

Introduction

It seems clear that two sorts of closely-connected questions will need to be addressed very specifically in future deliberations.

First, what specific capabilities are needed if North Carolina is to become an "A" state? Second, what expenditures must be made at what times for these capabilities to be put into place?

The very rough preliminary attached figures are presented to stimulate further focussed consideration of specific answers to these questions. An overall timeframe of five years was chosen based on the premise that if North Carolina has not attained "A" status by 1989, it is likely to have missed the boat, to have lost its chance at a leadership role. The attached tables and figures are based on rough dollar amounts, which are intended at this time to give approximate order of magnitude of expenditures, for one possible plan. Obviously, not only the figures but the overall patterns of spending may be varied in different ways. However, the plan defined by these expenditures appears to present one reasonably straightforward approach, and, it is hoped, will prove useful in deliberations.

If North Carolina is to seize and hold national leadership in biotechnology, it seems likely that in five years, the year 1989, the component resources considered in the preceding text will in some form be present in the statewide picture. (Table I, IA, IB, IC: "Total and State Expenditures Allocated to Biotechnology Resources FY 1984-FY 1988"; Figure 1: "Allocation of Funds to Resources: People, Supportive Infrastructure and Facilities".) Individual components may be decided for or against, or modified; but the broad cumulative

base is most probably a necessity for a solid state effort. The process of attaining the "A" position by 1989 will demand significant investment of funds--by the state and by others--prior to 1989.

Hard analysis of these preliminary outlines should lead to establishment of priorities, some of which may be constrained by time. For example, a limited pool of potentially recruitable world-class scientists and engineers exists; universities in other states will be competing vigorously for those people. To some degree, the sooner N. C. aggressively recruits them, the better our state's chances will be. As another example, if it is hoped that some level of entrepreneurial activity will be reached by 1989, a supportive infrastructure must have been in place for some time prior to that. If it is decided that pilot plant facilities will serve the needs of universities, help generate some small companies, assist in the attraction of established firms moving into biotechnology, then earlier construction rather than later will allow a "snowball" effect to get into action. The visibility and credibility of a strong state effort may have particular importance at a particular time. These sorts of considerations, viewed in light of the overall economy of the state, may lead to a time frame of expected funding and accomplishments.

Two alternatives to the time frame of the proposed plan, the one which is derived from the attached figures, are sketched in Figure 2: "Spending Alternatives Over Time"; earlier substantial investment is portrayed in one alternative, postponed investment in the other. Whatever time frame is chosen for action, however, it is assumed that roughly the same amount of expenditures must have been made by the end of FY 1988 for North Carolina to have its full program in place. Thereafter, costs to sustain the program may be borne primarily by non-state funds.

V. PROPOSED SOURCES AND CHANNELS OF RESOURCES

A. Sources

The premise throughout this document is that, if North Carolina is to achieve a truly cohesive, broad based initiative in biotechnology, one which will entail extensive industrial development in the state, significant investment by the state government will be required additional to what is currently being spent. In addition to "getting the job done", this extraordinary level of commitment by the state will signal to the world that biotechnology activity is both welcome and nurtured in North Carolina.

Other funds are and will be available for biotechnology. Funding from the private sector can be aggressively pursued, as experiences of the North Carolina Biotechnology Center to date demonstrate. Far more is possible, particularly with more funds to "leverage" matches. Federal agency and foundation funding is also available. For example, the Monoclonal Lymphocyte Technology Center currently being developed as a multi-university center administratively supported by the North Carolina Biotechnology Center, has already brought in federal funding and is expected to become self-supporting with at least a half million dollars per year from the private sector. In short, matching or even seed funding from the state, particularly when used in creative programs and projects, can draw forth far greater amounts of outside funding.

An attempt is made here, in developing rough figures for components of the overall picture, to reflect ways in which federal, foundation, and private sector funding will contribute to many costs. (Table II: "Funding Sources by Year".) If quality is in fact sought, and programs creatively organized, far

more should thus be accomplished than the absolute value of state dollars alone and programs creatively organized, far more should thus be accomplished than the absolute value of state dollars alone would indicate. (Figure 3: "Sources of Funds for Biotechnology in North Carolina".) Each world-class researcher added to the state, for instance, while receiving salary and perhaps \$100,000, of initial research support from the state, may bring hundreds of thousands per year in federal grants as well as several postdoctoral fellows. Programs of interest to industry should, if properly organized, receive funds from the private sector, and an attempt is made to reflect this substantive interaction. Furthermore, of course, the establishment of private facilities in North Carolina by biotechnology-related firms does not even enter into the figures presented here, but should prove to be the truly significant contribution to the state in terms of return on dollars invested.

Thus, if handled successfully, the investment by the state should leverage far greater funds. A sixty million dollar investment by the state in biotechnology over 5 years might give rise to, for instance, a total investment three times that amount. To add perspective in the total expenditure of the state it might be considered here that one company (Hoechst) funding research at one university-affiliated hospital (Massachusetts General Hospital) provided some 50 million dollars over a five year period. Monsanto has a 23.5 million dollar agreement with one university (Washington University) over a five year period. Michigan's state government is already investing a minimum of \$6 million dollars/per year in a five year total of \$30 million dollars. By interweaving academic, private and public sector activities as well as dollars, however, North Carolina's investment can lead to a far higher level of return.

B. Channels of Resources

Of course, some of the most difficult problems that arise whenever funding is considered have to do with distribution of funds. What channels will be the most effective, as well as the most appropriate, for funding directed toward certain ends? Further dialogue among concerned public and private institutions, the private sector, the North Carolina Biotechnology Center and the Committee will be needed to answer this question; the answer may well lie in a deliberate mixture of channels.

Some general points are likely to prove valid. Public institutions will be able to receive funding through: 1) competitive processes for fellowships, grants, etc., perhaps handled by the North Carolina Biotechnology Center; 2) joint efforts of public and private university researchers assisted by the North Carolina Biotechnology Center; 3) Central Research facilities; 4) conference and symposia; and 5) budget requests submitted through normal channels to the Legislature. Private universities are more likely to participate through 1) competitive processes for fellowships, grants, etc.; 2) joint efforts; 3) Central research facilities; and 4) conferences and symposia. Other organizational entities will doubtless have a role to play. Furthermore, commercial firms will benefit somewhat less directly but no less significantly from state allocations which stimulate a positive funding initiative in biotechnology. Further dialogue will bring these possibilities into sharper focus.

C. Summary of Rationale Concerning Resources

The premises on which this discussion has been built are straightforward.

- 1) Past investment by the state in high quality research and education has brought the state to a strong, if not yet leadership, position in biotechnology.
- 2) Because this broad base exists, along with more recent experiments in supportive infrastructures and interweaving of resources, North Carolina has an unparalleled opportunity to serve a leadership role in developing technology which will have a dramatically significant impact on the economy of the future.
- 3) With some reaonable level of investment, the state can leverage other funds to create a funding situation so substantive as to carry a unique initiative in biotechnology.
- 4) If appropriately and creatively approached, a comprehensive interwoven initiative unlike any other will make North Carolina an "A" state within 5 years--a state recognized as a natural home for industrial development in biotechnology.

TABLE I

TOTAL AND STATE EXPENDITURES ALLOCATED TO BIOTECHNOLOGY RESOURCES FY 1984-88*

RESOURCE	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY 1984-1988	FY 1989**
PEOPLE							
Total Expenditures	628,000	4,816,000	8,256,000	11,008,000	13,760,000	38,468,000	13,760,000
New State Appropriations	628,000	1,850,800	3,172,800	4,230,400	5,288,000	15,170,000	5,288,000
SUPPORTIVE INFRASTRUCTURE							
Total Expenditures	3,580,000	14,105,000	21,945,000	28,335,000	35,275,000	103,240,000	34,275,000
New State Appropriations	1,113,000	2,771,000	3,012,000	3,152,000	3,642,000	13,690,000	2,642,000
FACILITIES							
Total Expenditures		11,300,000	11,050,000	8,160,000	7,860,000	38,370,000	860,000
New State Appropriations		9,962,500	9,837,500	6,232,500	6,007,500	32,040,000	445,000
TOTAL EXPENDITURES							
NEW STATE APPROPRIATIONS	4,208,000	30,221,000	41,251,000	47,503,000	56,895,000	180,078,000	48,895,000
	1,741,000	14,584,300	16,022,300	13,614,900	14,937,500	60,900,000	8,375,000

*These funds are all additional to current funding. University reorientation of existing funds is not listed as a source here because it is assumed throughout these figures that this is already going on, complementary to the additional effort described here. (For example, at a minimum, between 10 and 20 faculty positions filled within the last three years in the UNC system have been oriented toward biotechnology.)

**Sustaining costs not included in 5 year total

TABLE 1A

PEOPLE

RESOURCE	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY 1984-1988	FY 1989*
WORLD CLASS SCIENTISTS & ENGINEERS							
Total Expenditures	4	7	12	16	20		20
New State Appropriations	400,000	700,000	1,200,000	1,600,000	2,000,000	5,900,000	2,000,000
	400,000	700,000	1,200,000	1,600,000	2,000,000	5,900,000	2,000,000
YOUNG EXCELLENT SCIENTISTS & ENGINEERS							
Total Expenditures		21	36	48	60		60
New State Appropriations		1,050,000	1,800,000	2,400,000	3,000,000	8,250,000	3,000,000
		1,050,000	1,800,000	2,400,000	3,000,000	8,250,000	3,000,000
POSTDOCTORAL FELLOWS, including targeted programs	10	77	132	176	220		220
Total Expenditures	160,000	1,232,000	2,112,000	2,816,000	3,520,000	9,840,000	3,520,000
New State Appropriations	160,000	61,600	105,600	140,800	176,000	644,000	176,000
GRADUATE STUDENTS, including targeted programs	8	98	168	224	280		280
Total Expenditures	68,000	784,000	1,344,000	1,792,000	2,240,000	6,228,000	2,240,000
New State Appropriations	68,000	39,200	67,200	89,600	112,000	376,000	112,000
TECHNICAL PERSONNEL							
Total Expenditures		42	72	96	120		120
New State Appropriations		1,050,000	1,800,000	2,400,000	3,000,000	8,250,000	3,000,000
		-0-	-0-	-0-	-0-	-0-	-0-
TOTAL EXPENDITURES	628,000	4,816,000	8,256,000	11,008,000	13,760,000	38,468,000	13,760,000
NEW STATE APPROPRIATIONS	628,000	1,850,800	3,172,800	4,230,400	5,288,000	15,170,000	5,288,000

*(sustaining costs not included in 5 year total)

SUPPORTIVE INFRASTRUCTURES

RESOURCE	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY 1984-1988	FY 1989*
START UP RESEARCH FUNDS							
newly recruited scientists and engineers (one time/individual 100,000 x wc 50,000 x y)	400,000	1,350,000	1,250,000	1,000,000	1,000,000	5,000,000	-
New State Appropriations	400,000	1,350,000	1,250,000	1,000,000	1,000,000	5,000,000	-
SUSTAINING RESEARCH							
each year subsequent to hiring (700,000/wc; 250,000/y)	2,100,000	10,150,000	17,400,000	23,200,000	29,000,000	81,850,000	29,000,000
New State Appropriations	-0-	-0-	-0-	-0-	-0-	-0-	-0-
SEED \$ RESEARCH IN NEW DIRECTIONS (250,000/yr)	-0-	250,000	250,000	250,000	250,000	1,000,000	250,000
New State Appropriations	-0-	250,000	250,000	250,000	250,000	1,000,000	250,000
COURSE SUPPORT-200,000/yr (5 courses x 40,000)	80,000	80,000	120,000	160,000	200,000	640,000	200,000
New State Appropriations	80,000	80,000	120,000	160,000	200,000	640,000	200,000
APPROPRIATE INSTITUTIONAL POLICIES	-0-	-	-	-	-	-	-
ENTREPRENEURIAL SEED							
CAPITAL (20 individuals x \$75,000)	75,000	450,000	600,000	900,000	1,500,000	3,525,000	1,500,000
New State Appropriations	25,000	150,000	200,000	300,000	500,000	1,175,000	500,000
ENTREPRENEURIAL SUPPORT (\$75,000/yr)	75,000	75,000	75,000	75,000	75,000	375,000	75,000
New State Appropriations	75,000	75,000	75,000	75,000	75,000	375,000	75,000
DEPARTMENT OF COMMERCE							
Targeting Efforts	-	50,000	50,000	50,000	50,000	200,000	50,000
New State Appropriations	-	50,000	50,000	50,000	50,000	200,000	50,000
MEANS FOR MOBILIZING RESOURCES (\$3,000,000/yr)	750,000	1,500,000	2,000,000	2,500,000	3,000,000	9,750,000	3,000,000
New State Appropriations	500,000	750,000	1,000,000	1,250,000	1,500,000	5,000,000	1,500,000
CONFERENCES, SYMPOSIA (\$200,000/yr)	100,000	200,000	200,000	200,000	200,000	900,000	200,000
New State Appropriations	33,000	66,000	67,000	67,000	67,000	300,000	67,000
TOTAL EXPENDITURES	3,580,000	14,105,000	21,945,000	28,335,000	35,275,000	103,240,000	34,275,000
NEW STATE APPROPRIATIONS	1,113,000	2,771,000	3,012,000	3,152,000	3,642,000	13,690,000	2,642,000

*(sustaining costs not included in 5 year total)

TABLE IC

FACILITIES

RESOURCE	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY 1984-1988	FY 1989*
FERMENTATION PILOT PLANT (\$2,000,000 start up; 500,000/yr operating)							
Total Expenditures		1,000,000	1,500,000	500,000	500,000	3,500,000	500,000
New State Appropriations		500,000	750,000	250,000	250,000	1,750,000	250,000
INCUBATOR/R&D CENTER FACILITIES (\$750,000 start up: 300,000/yr operating)							
Total Expenditures		1,050,000	300,000	300,000	300,000	1,950,000	300,000
New State Appropriations		525,000	150,000	150,000	150,000	975,000	150,000
R&D SPACE (\$250/sq.ft. x 120,000 sq.ft.)							
Total Expenditures		8,750,000	8,750,000	5,000,000	5,000,000	27,500,000	-
New State Appropriations		8,750,000	8,750,000	5,000,000	5,000,000	27,500,000	-
SPECIALIZED EQUIPMENT							
Total Expenditures		500,000	500,000	500,000	500,000	2,000,000	-
New State Appropriations		187,500	187,500	187,500	187,500	750,000	-
SMALL CONFERENCE CENTER (3M start up; self- sustaining)							
Total Expenditures				1,500,000	1,500,000	3,000,000	-
New State Appropriations				375,000	375,000	750,000	-
COMPUTER NETWORK (\$300,000 computer; 60,000/yr. operating)							
Total Expenditures				360,000	60,000	420,000	60,000
New State Appropriations				270,000	45,000	315,000	45,000
TOTAL EXPENDITURES		11,300,000	11,050,000	8,160,000	7,860,000	38,370,000	860,000
NEW STATE APPROPRIATIONS		9,962,500	9,837,500	6,232,500	6,007,500	32,040,000	445,000

*(sustaining costs not included in 5 year total)

TABLE II

FUNDING SOURCES BY YEAR

RESOURCE	FY 1984	FY 1985	FY 1986	FY 1987	FY 1988	FY 1984-1988	FY 1989
PEOPLE							
Private Sector							
Federal		100,800	172,800	230,400	288,000	792,000	288,000
State	628,000	2,864,400	4,910,400	6,547,200	8,184,000	22,506,000	8,184,000
		1,850,800	3,172,800	4,230,400	5,288,000	15,170,000	5,288,000
SUPPORTIVE INFRASTRUCTURE							
Private Sector	246,500	778,500	1,017,000	1,304,500	1,691,000	5,037,500	1,691,000
Federal	2,220,500	10,555,500	17,916,000	23,878,500	29,942,000	84,512,500	29,942,000
State	1,113,000	2,771,000	3,012,000	3,152,000	3,642,000	13,690,000	2,642,000
FACILITIES							
Private Sector		962,500	775,000	1,570,000	1,532,500	4,840,000	345,000
Federal		375,000	437,500	357,500	320,000	1,490,000	70,000
State		9,962,500	9,837,500	6,232,500	6,007,500	32,040,000	445,000
TOTAL							
Private Sector	246,500	1,841,800	1,964,800	3,104,900	3,511,500	10,669,500	2,324,000
Federal	2,220,500	13,794,900	23,263,900	30,783,200	38,446,000	108,508,500	38,196,000
State	1,741,000	14,584,300	16,022,300	13,614,900	14,937,500	60,900,000	8,375,000
TOTAL	4,208,000	30,221,000	41,251,000	47,503,000	56,895,000	180,078,000	48,895,000

Figure 1.

ALLOCATION OF FUNDS TO RESOURCES: PEOPLE, SUPPORTIVE INFRASTRUCTURE AND FACILITIES

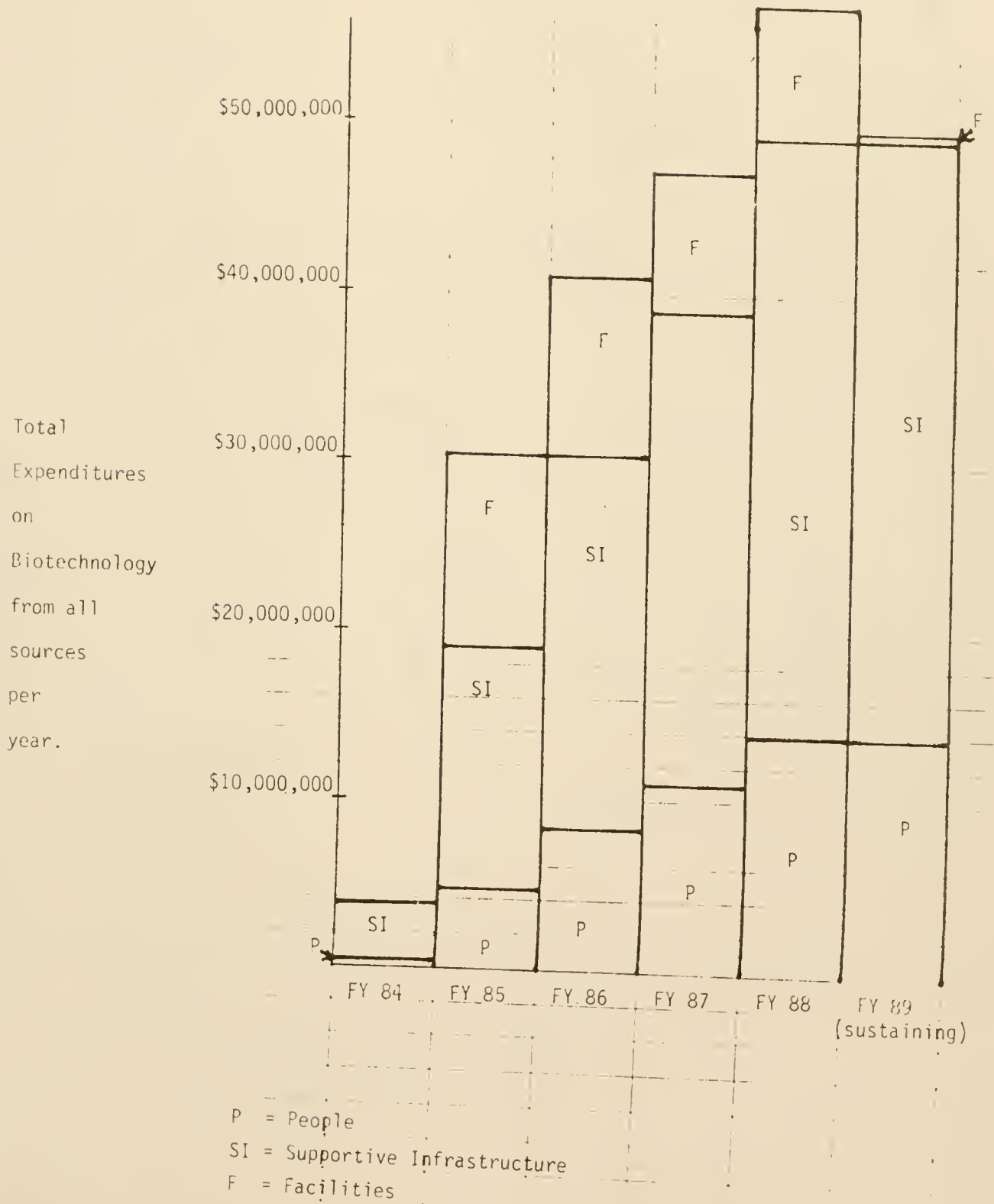


Figure 2.

SPENDING ALTERNATIVES OVER TIME

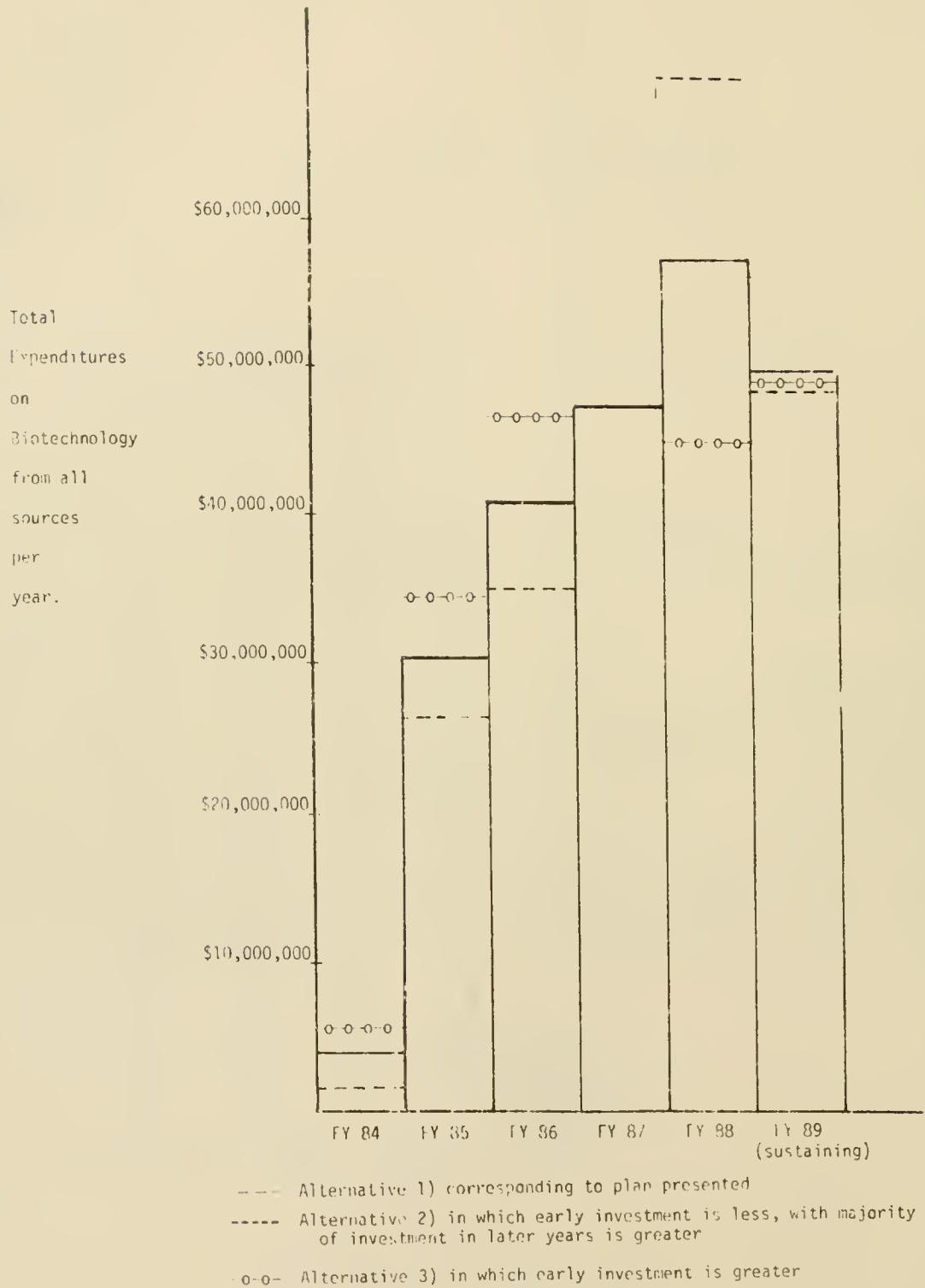


Figure 3.

SOURCES OF FUNDS FOR BIOTECHNOLOGY IN NORTH CAROLINA

Total
Expenditures
on
Biotechnology
from all
sources
per
year.

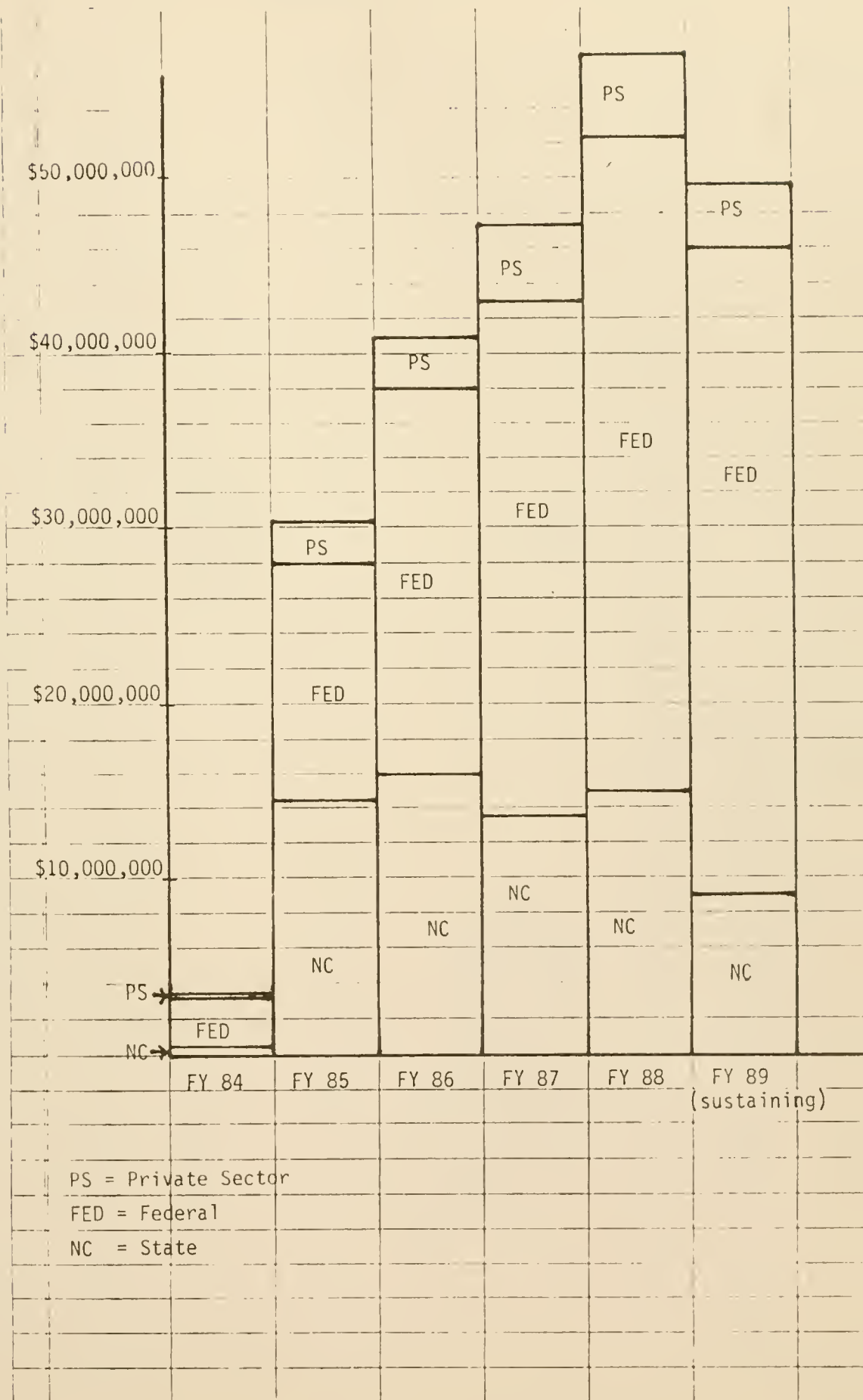


TABLE 1. ESTIMATED ANNUAL RETURNS OF RESEARCH AND EXTENSION
INVESTEMENTS IN U.S. AGRICULTURE

TIME PERIOD	ANNUAL RATE OF RETURN
1927 - 1950	
AGRICULTURAL RESEARCH	
TECHNOLOGY - ORIENTED	95%
SCIENCE - ORIENTED	110%

SOURCE: EVENSON, RUTTAN, AND WAGGONER, 1979

TABLE 2. ESTIMATED ANNUAL RETURNS OF RESEARCH AND
EXTENSION INVESTMENTS IN U.S. AGRICULTURE

TIME PERIOD	ANNUAL RATE OF RETURN (%)
1948 - 1971	
AGRICULTURAL RESEARCH	
TECHNOLOGY - ORIENTED	
- SOUTH	130
- NORTH	93
- WEST	95
SCIENCE - ORIENTED	45
FARM MANAGEMENT AND AGRICULTURAL EXTENSION	110

SOURCE: EVENSON, RUTTAN, AND WAGGONER, 1979

TABLE 3. ESTIMATED IMPACTS OF RESEARCH AND EXTENSION
INVESTMENTS IN U.S. AGRICULTURE

TIME PERIOD	ANNUAL RATE OF RETURN (%)	PERCENT OF PRODUCTIVITY CHANGE REALIZED IN THE STATE UNDERTAKING THE RESEARCH
1927 - 1950		
AGRICULTURAL RESEARCH		
TECHNOLOGY - ORIENTED	95	55
SCIENCE - ORIENTED	110	33

SOURCE: EVENSON, RUTTAN, AND WAGGONER, 1979

TABLE 4. ESTIMATED IMPACTS OF RESEARCH AND EXTENSION
INVESTMENTS IN U.S. AGRICULTURE

TIME PERIOD	ANNUAL RATE OF RETURN (%)	PERCENT OF PRODUCTIVITY CHANGE REALIZED IN THE STATE UNDERTAKING THE RESEARCH
1948 - 1971		
AGRICULTURAL RESEARCH		
TECHNOLOGY - ORIENTED		
- SOUTH	130	67
- NORTH	93	43
- WEST	95	67
SCIENCE - ORIENTED	45	32
FARM MANAGEMENT AND AGRICULTURAL EXTENSION	110	100

SOURCE: EVENSON, RUTTAN, AND WAGGONER, 1979

